INCEPT
The Intensive Care Platform Trial

PLACE IN SITE FILE #7.1

Copy of eCRF from the EasyRF

Version 1.2

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INCEPT

INCEPT - screening

Form type: Screening
Follows clinical day: No
Timing: 0.0 seconds after Screening for INCEPT
Span: 0 seconds
Location(s): Trial Site

Inclusion Criteria

Age ≥ 18 years [description]

Name: age_ge_18

Lifespan: 0 seconds

- ○ Yes
- ○ No

Acutely admitted to the ICU [description]

Name: acute_admission

Lifespan: 0 seconds

- ○ Yes
- ○ No

Exclusion Criteria

Informed consent following inclusion expected to be unobtainable [description]

Name: informed_content_unobtainable

Lifespan: 0 seconds

- ○ Yes
- ○ No

Patient is under coercive measures [description]

Name: coercive_measures

Lifespan: 0 seconds

- ○ Yes
- ○ No

INCEPT-Albumin

INCEPT-Albumin - 30/90 days followup

Form type: 30/90/180 days followup

Follows clinical day: No

Timing: 30.0, 90.0 days after Enrolment for INCEPT-Albumin

Span: 0 seconds

Location(s): Trial Site, Non-trial site, Out of hospital

Outcomes - other

Please confirm that the participant’s medical record has been assessed for death or any new admissions, and that any new events have been added to the event history. [description]

Name: 30_90_day_followup

Lifespan: 0 seconds

- ○ Yes
- ○ Unknown

INCEPT-Albumin - baseline

Form type: Baseline

Follows clinical day: No

Timing: 0.0 days after Enrolment for INCEPT-Albumin

Span: 0 seconds

Location(s): Trial Site

Therapies - fluid

IV crystalloid volumes within the last 24 hours before enrolment [description]

Name: crystalloid_volumes_within_24h

Lifespan: 30 minutes

Minimum value: 0

Maximum value: 30000

Plausible minimum: 0

Plausible maximum: 15000

[ ] mL

- ☐ Unknown

Acute diseases/conditions

Shock type - composite [description]

Name: shock_type_composite

Lifespan: 0 seconds

Conditions:

• Is sepsis the primary cause of shock: No

Primary cause of shock [description]

Name: primary_cause_of_shock

Lifespan: 0 seconds

- ○ Cardiogenic shock
- ○ Haemorrhagic or traumatic shock
- ○ Neurogenic shock
- ○ Anaphylactic shock
- ○ Burn shock
- ○ Obstructive shock
- ○ Hypovolaemic shock due to fluid loss

Biochemistry

Lowest P-albumin within the last 24 hours prior to randomisation [description]

Name: lowest_p_albumin_within_24h

Lifespan: 2 hours

Minimum value: 1.0

Maximum value: 115.0

Plausible minimum: 6.0

Plausible maximum: 45.0

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g/L

☐ Unknown

INCEPT-Albumin - dayform 1-90

Form type: Dayform

Follows clinical day: Yes

Timing: 1st, 2nd, 3rd, 4th, 5th, 6th, 7th, 8th, 9th, 10th, 11th, 12th, 13th, 14th, 15th, 16th, 17th, 18th, 19th, 20th, 21st, 22nd, 23rd, 24th, 25th, 26th, 27th, 28th, 29th, 30th, 31st, 32nd, 33rd, 34th, 35th, 36th, 37th, 38th, 39th, 40th, 41st, 42nd, 43rd, 44th, 45th, 46th, 47th, 48th, 49th, 50th, 51st, 52nd, 53rd, 54th, 55th, 56th, 57th, 58th, 59th, 60th, 61st, 62nd, 63rd, 64th, 65th, 66th, 67th, 68th, 69th, 70th, 71st, 72nd, 73rd, 74th, 75th, 76th, 77th, 78th, 79th, 80th, 81st, 82nd, 83rd, 84th, 85th, 86th, 87th, 88th, 89th, 90th day after Enrolment for INCEPT-Albumin

Span: 1 day

Location(s): Trial Site

Serious adverse reactions and other relevant events

Major bleeding on this day - composite [description]

Name: major_bleeding_on_this_day_composite

Lifespan: 0 seconds

Conditions:

- Major bleeding on this day: Yes

Type of major bleeding - composite [description]

Name: type_of_major_bleeding_composite

Lifespan: 0 seconds

Conditions:

- Type of major bleeding: Symptomatic bleeding

Site of bleeding [description]

Name: site_of_bleeding

Lifespan: 0 seconds

- ☐ Intracranial
- ☐ Intraspinal
- ☐ Intraocular
- ☐ Retroperitoneal
- ☐ Intraarticular
- ☐ Pericardial
- ☐ Intramuscular with compartment syndrome

Conditions:

- Type of major bleeding: Bleeding that requires intervention

Type of intervention [description]

Name: type_of_intervention

Lifespan: 0 seconds

- ☐ Transfusion of ≥400ml whole blood or red cells
- ☐ Endoscopy
- ☐ Endovascular management
- ☐ Surgery

Severe anaphylactic reaction to albumin on this day [description]

Name: severe_anaphylatic_reaction_to_albumin_on_this_day

Lifespan: 0 seconds

- ○ Yes
- ○ No
- ○ Unknown

Therapies - fluid

Volume of albumin 5% (or lower concentration) on this day [description]

Name: albumin_volume_5percent

Lifespan: 0 seconds

Minimum value: 0

Maximum value: 9999

Plausible minimum: 0

Plausible maximum: 4999

[ ] mL

- ☐ Unknown

Volume of albumin 20% (or higher concentration) on this day [description]

Name: albumin_volume_20percent

Lifespan: 0 seconds

Minimum value: 0

Maximum value: 4999

Plausible minimum: 0

Plausible maximum: 1999

mL

☐ Unknown

Total volume of packed red blood cells on this day [description]

Name: total_volume_rbc
Lifespan: 0 seconds
Minimum value: 0
Maximum value: 29999
Plausible minimum: 0
Plausible maximum: 9999

mL

☐ Unknown

Total fluid input on this day [description]

Name: total_fluid_input
Lifespan: 0 seconds
Minimum value: 0
Maximum value: 39999
Plausible minimum: 0
Plausible maximum: 9999

mL

☐ Unknown

Total fluid balance on this day [description]

Name: total_fluid_balance
Lifespan: 0 seconds
Minimum value: -19999
Maximum value: 19999
Plausible minimum: -9999
Plausible maximum: 9999

mL

☐ Unknown

Protocol adherence

Protocol violation in the albumin domain on this day [description]

Name: protocol_violation_albumin

Lifespan: 0 seconds

- ○ Yes
- ○ No
- ○ Unknown

INCEPT-Albumin - dayform non-trial site 1-90

Form type: Non-trial site dayform

Follows clinical day: Yes

Timing: 1st, 2nd, 3rd, 4th, 5th, 6th, 7th, 8th, 9th, 10th, 11th, 12th, 13th, 14th, 15th, 16th, 17th, 18th, 19th, 20th, 21st, 22nd, 23rd, 24th, 25th, 26th, 27th, 28th, 29th, 30th, 31st, 32nd, 33rd, 34th, 35th, 36th, 37th, 38th, 39th, 40th, 41st, 42nd, 43rd, 44th, 45th, 46th, 47th, 48th, 49th, 50th, 51st, 52nd, 53rd, 54th, 55th, 56th, 57th, 58th, 59th, 60th, 61st, 62nd, 63rd, 64th, 65th, 66th, 67th, 68th, 69th, 70th, 71st, 72nd, 73rd, 74th, 75th, 76th, 77th, 78th, 79th, 80th, 81st, 82nd, 83rd, 84th, 85th, 86th, 87th, 88th, 89th, 90th day after Enrolment for INCEPT-Albumin

Span: 1 day

Location(s): Non-trial site

Serious adverse reactions and other relevant events

Major bleeding on this day - composite [description]

Name: major_bleeding_on_this_day_composite

Lifespan: 0 seconds

Conditions:

• Major bleeding on this day: Yes

Type of major bleeding - composite [description]

Name: type_of_major_bleeding_composite

Lifespan: 0 seconds

Conditions:

• Type of major bleeding: Symptomatic bleeding

Site of bleeding [description]

Name: site_of_bleeding

Lifespan: 0 seconds

- ☐ Intracranial
- ☐ Intraspinal
- ☐ Intraocular
- ☐ Retroperitoneal
- ☐ Intraarticular
- ☐ Pericardial
- ☐ Intramuscular with compartment syndrome

Conditions:

• Type of major bleeding: Bleeding that requires intervention

Type of intervention [description]

Name: type_of_intervention

Lifespan: 0 seconds

- ☐ Transfusion of ≥400ml whole blood or red cells
- ☐ Endoscopy
- ☐ Endovascular management
- ☐ Surgery

INCEPT-Albumin - followup (death)

Form type: 30/90/180 days followup

Follows clinical day: Yes

Timing: 180th day after Enrolment for INCEPT-Albumin

Span: 1 day

Location(s): Trial Site, Non-trial site, Out of hospital

Outcomes - other

Please confirm that the participant's medical record has been assessed for death, and that the event has been entered in the event history if so [description]

Name: death_before_day_180

Lifespan: 0 seconds

- ○ Yes
- ○ Unknown

INCEPT-Albumin - screening

Form type: Screening
Follows clinical day: No
Timing: 0.0 seconds after Screening for INCEPT-Albumin
Span: 0 seconds
Location(s): Trial Site

Inclusion Criteria

Ongoing infusion of a vasopressor or inotropic agent [description]

Name: ongoing_vasopressor_or_inotropic_agent
Lifespan: 0 seconds

- ○ Yes
- ○ No

Plasma lactate ≥ 2 mmol/L in any blood sample performed within the last 3 hours [description]

Name: lactate_more_than_or_equal_to_2
Lifespan: 0 seconds

- ○ Yes
- ○ No

Exclusion Criteria

Received albumin during the current ICU stay [description]

Name: received_albumin_during_the_current_icu_stay
Lifespan: 0 seconds

- ○ Yes
- ○ No

Traumatic brain injury [description]

Name: traumatic_brain_injury

Lifespan: 0 seconds

- ○ Yes
- ○ No

Known pregnancy [description]

Name: known_pregnancy

Lifespan: 0 seconds

- ○ Yes
- ○ No

Known albumin allergy [description]

Name: known_albumin_allergy

Lifespan: 0 seconds

- ○ Yes
- ○ No

Religious objection to administration of albumin [description]

Name: religious_objection_to_albumin

Lifespan: 0 seconds

- ○ Yes
- ○ No

Inclusion in another interventional trial or INCEPT domain where co-enrolment with the INCEPT-Albumin domain is not permitted. [description]

Name: inclusion_in_another_trial_where_coenrolment_with_incept_albumin_is_not_acceptable

Lifespan: 0 seconds

- ○ Yes
- ○ No

Stratification Variables

Site [description]

Name: site

Lifespan: 0 seconds

Is sepsis the primary cause of shock [description]

Name: septic_shock

Lifespan: 0 seconds

- ○ Yes
- ○ No

Additional Variables

Presence of haematological or metastatic cancer [description]

Name: haematological_or_metastatic_cancer

Lifespan: 2 days

- ○ Yes
- ○ No

Date of birth [description]

Name: date_of_birth

Lifespan: 1 year

Minimum value: 115 years ago

Maximum value: 18 years ago

Plausible minimum: 100 years ago

Sex [description]

Name: sex

Lifespan: 1 year

- ○ Female

- ○ Male

Acute surgery within 7 days [description]

Name: acute_surgical_admission

Lifespan: 12 hours

- ○ Yes
- ○ No

Use of invasive mechanical ventilation at the time of randomisation [description]

Name: use_of_invasive_mechanical_ventilation_at_randomisation

Lifespan: 30 minutes

- ○ Yes
- ○ No

Use of renal replacement therapy within the last 72 hours prior to randomisation [description]

Name: rrt_within_72h_before_randomisation

Lifespan: 0 seconds

- ○ Yes
- ○ No

INCEPT-Thromboprophylaxis

INCEPT-Thromboprophylaxis - baseline

Form type: Baseline

Follows clinical day: No

Timing: 0.0 days after Enrolment for INCEPT-Thromboprophylaxis

Span: 0 seconds

Location(s): Trial Site

Biochemistry

Lowest platelet count in the 24 hours prior to randomisation [description]

Name: lowest_platelet_count_24h_prior_to_randomisation

Lifespan: 0 seconds

Minimum value: 0

Maximum value: 2000

Plausible minimum: 10

Plausible maximum: 400

10^9/L

☐ Unknown

INCEPT-Thromboprophylaxis - dayform 0-90

Form type: Dayform

Follows clinical day: Yes

Timing: 1st, 2nd, 3rd, 4th, 5th, 6th, 7th, 8th, 9th, 10th, 11th, 12th, 13th, 14th, 15th, 16th, 17th, 18th, 19th, 20th, 21st, 22nd, 23rd, 24th, 25th, 26th, 27th, 28th, 29th, 30th, 31st, 32nd, 33rd, 34th, 35th, 36th, 37th, 38th, 39th, 40th, 41st, 42nd, 43rd, 44th, 45th, 46th, 47th, 48th, 49th, 50th, 51st, 52nd, 53rd, 54th, 55th, 56th, 57th, 58th, 59th, 60th, 61st, 62nd, 63rd, 64th, 65th, 66th, 67th, 68th, 69th, 70th, 71st, 72nd, 73rd, 74th, 75th, 76th, 77th, 78th, 79th, 80th, 81st, 82nd, 83rd, 84th, 85th, 86th, 87th, 88th, 89th, 90th day after Enrolment for INCEPT-Thromboprophylaxis

Span: 1 day

Location(s): Trial Site

Serious adverse reactions and other relevant events

Venous thromboembolism on this day - composite [description]

Name: venous_thromboembolism_on_this_day_composite

Lifespan: 0 seconds

Conditions:

- Venous thromboembolism on this day: Yes

Type of venous tromboembolism - composite [description]

Name: type_of_tromboembolism_composite

Lifespan: 0 seconds

Conditions:

- Type of venous tromboembolism: Pulmonary embolism

The anatomical location of the pulmonary embolism [description]

Name: location_of_pe

Lifespan: 0 seconds

- ☐ Central artery
- ☐ Lobar artery
- ☐ Segmental artery
- ☐ Subsegmental artery

Presence of a central venous catheter [description]

Name: presence_of_a_central_venous_catheter

Lifespan: 0 seconds

- ○ Yes
- ○ No

The imaging modality used to detect the pulmonary embolism [description]

Name: imaging_modality_pe

Lifespan: 0 seconds

- ☐ CT angiography
- ☐ High probability ventilation-perfusion scan

Start of treatment with therapeutic dose anticoagulation < 24h after diagnosis [description]

Name: start_therapeutic_dose_anticoagulation_24h

Lifespan: 0 seconds

- ○ Yes
- ○ No

Conditions:

- Type of venous tromboembolism: Deep venous thrombosis

The anatomical location of the DVT [description]

Name: location_of_dvt

Lifespan: 0 seconds

- ☐ Iliac vein
- ☐ Femoral vein
- ☐ Popliteal vein
- ☐ Distal deep vein of the lower extremity
- ☐ Internal jugular vein
- ☐ Brachiocephalic vein
- ☐ Subclavian vein
- ☐ Axillary vein
- ☐ Distal deep vein of the upper extremity

Presence of a central venous catheter in the same vein as the DVT during the 24 hours before the event [description]

Name: presence_of_a_central_venous_catheter_in_relation_to_dvt

Lifespan: 0 seconds

- ○ Yes
- ○ No

The imaging modality used to detect the deep venous trombosis [description]

Name: imaging_modality_dvt

Lifespan: 0 seconds

- ☐ Point-of-care ultrasound
- ☐ Compression ultrasound
- ☐ Venography
- ☐ Computed tomography (CT)
- ☐ Magnetic resonance imaging (MRI)

The professional who performs the procedure that leads to the diagnosis [description]

Name: professional

Lifespan: 0 seconds

- ○ ICU professional

○ Radiology professional

Start of treatment with therapeutic dose anticoagulation < 24h after diagnosis [description]

Name: start_therapeutic_dose_anticoagulation_24h

Lifespan: 0 seconds

○ Yes
○ No

Major bleeding on this day - composite [description]

Name: major_bleeding_on_this_day_composite

Lifespan: 0 seconds

Conditions:

• Major bleeding on this day: Yes

Type of major bleeding - composite [description]

Name: type_of_major_bleeding_composite

Lifespan: 0 seconds

Conditions:

• Type of major bleeding: Symptomatic bleeding

Site of bleeding [description]

Name: site_of_bleeding

Lifespan: 0 seconds

☐ Intracranial
☐ Intraspinal
☐ Intraocular
☐ Retroperitoneal
☐ Intraarticular
☐ Pericardial
☐ Intramuscular with compartment syndrome

Conditions:

• Type of major bleeding: Bleeding that requires intervention

Type of intervention [description]

Name: type_of_intervention

Lifespan: 0 seconds

- ☐ Transfusion of ≥400ml whole blood or red cells
- ☐ Endoscopy
- ☐ Endovascular management
- ☐ Surgery

Severe anaphylactic reaction to LMWH on this day [description]

Name: severe_anaphylatic_reaction_to_lmwh_on_this_day

Lifespan: 0 seconds

- ○ Yes
- ○ No
- ○ Unknown

Heparin induced thrombocytopenia (HIT) on this day [description]

Name: heaprin_induced_thrombocytopenia_on_this_day

Lifespan: 0 seconds

- ○ No HIT
- ○ Possible HIT
- ○ Definite HIT
- ○ Unknown

Protocol adherence

Administration of the site-preferred LMWH in the allocated dose on this day - composite [description]

Name: administration_site_preferred_lmwh_on_this_day_composite

Lifespan: 0 seconds

Conditions:

- Administration of the site-preferred LMWH in the allocated dose on this day: No

Deviation from the allocated dose - composite [description]

Name: deviation_from_allocated_dose_composite

Lifespan: 0 seconds

Conditions:

- Deviation from the allocated dose: No
- Administered LMWH: None

Reason for deviation, one or more of the following [description]

Name: reason_for_deviation

Lifespan: 0 seconds

- ☐ Acute or chronic kidney injury
- ☐ Renal replacement therapy
- ☐ Invasive procedure
- ☐ Thrombocytopenia
- ☐ Use of thrombolysis
- ☐ Active bleeding
- ☐ Start of therapeutic anticoagulation, e.g. for VTE or atrial fibrillation
- ☐ Serious adverse reaction (e.g., LMWH-induced anaphylaxis or heparin-induced thrombocytopenia)
- ☐ Dose scheduled, but not administered because ICU admission occurred after, or ICU discharge occurred before, the scheduled dosing time
- ☐ Participation ended due to withdrawal of consent, discontinuation of active therapy, involuntary hospitalization, or a clinical decision
- ☐ Trial site not active in the thromboprophylaxis domain
- ☐ Dose adjustment (or temporary withholding of dose) for another reason

Conditions:

- Administered LMWH: None
- Deviation from the allocated dose: Yes

Reason for deviation, one or more of the following [description]

Name: reason_for_deviation

Lifespan: 0 seconds

- ☐ Acute or chronic kidney injury
- ☐ Renal replacement therapy
- ☐ Invasive procedure
- ☐ Thrombocytopenia

- ☐ Use of thrombolysis
- ☐ Active bleeding
- ☐ Start of therapeutic anticoagulation, e.g. for VTE or atrial fibrillation
- ☐ Serious adverse reaction (e.g., LMWH-induced anaphylaxis or heparin-induced thrombocytopenia)
- ☐ Dose scheduled, but not administered because ICU admission occurred after, or ICU discharge occurred before, the scheduled dosing time
- ☐ Participation ended due to withdrawal of consent, discontinuation of active therapy, involuntary hospitalization, or a clinical decision
- ☐ Trial site not active in the thromboprophylaxis domain
- ☐ Dose adjustment (or temporary withholding of dose) for another reason

Conditions:

• Administered LMWH: Enoxaparin

• Deviation from the allocated dose: Yes

Administered dose enoxaparin [description]

Name: administered_dose_enoxaparin

Lifespan: 0 seconds

Minimum value: 20

Maximum value: 600

mg

Reason for deviation, one or more of the following [description]

Name: reason_for_deviation

Lifespan: 0 seconds

- ☐ Acute or chronic kidney injury
- ☐ Renal replacement therapy
- ☐ Invasive procedure
- ☐ Thrombocytopenia
- ☐ Use of thrombolysis
- ☐ Active bleeding
- ☐ Start of therapeutic anticoagulation, e.g. for VTE or atrial fibrillation
- ☐ Serious adverse reaction (e.g., LMWH-induced anaphylaxis or heparin-induced thrombocytopenia)

- ☐ Dose scheduled, but not administered because ICU admission occurred after, or ICU discharge occurred before, the scheduled dosing time
- ☐ Participation ended due to withdrawal of consent, discontinuation of active therapy, involuntary hospitalization, or a clinical decision
- ☐ Trial site not active in the thromboprophylaxis domain
- ☐ Dose adjustment (or temporary withholding of dose) for another reason

Conditions:

• Administered LMWH: Dalteparin

• Deviation from the allocated dose: Yes

Administered dose dalteparin [description]

Name: administered_dose_dalteparin_in_iu

Lifespan: 0 seconds

Minimum value: 2500

Maximum value: 50000

IU

Reason for deviation, one or more of the following [description]

Name: reason_for_deviation

Lifespan: 0 seconds

- ☐ Acute or chronic kidney injury
- ☐ Renal replacement therapy
- ☐ Invasive procedure
- ☐ Thrombocytopenia
- ☐ Use of thrombolysis
- ☐ Active bleeding
- ☐ Start of therapeutic anticoagulation, e.g. for VTE or atrial fibrillation
- ☐ Serious adverse reaction (e.g., LMWH-induced anaphylaxis or heparin-induced thrombocytopenia)
- ☐ Dose scheduled, but not administered because ICU admission occurred after, or ICU discharge occurred before, the scheduled dosing time
- ☐ Participation ended due to withdrawal of consent, discontinuation of active therapy, involuntary hospitalization, or a clinical decision
- ☐ Trial site not active in the thromboprophylaxis domain

☐ Dose adjustment (or temporary withholding of dose) for another reason

Conditions:

- Administered LMWH: Nadroparin
- Deviation from the allocated dose: Yes

Administered dose nadroparin [description]

Name: administered_dose_nadroparin

Lifespan: 0 seconds

Minimum value: 1900

Maximum value: 38000

IU

Reason for deviation, one or more of the following [description]

Name: reason_for_deviation

Lifespan: 0 seconds

☐ Acute or chronic kidney injury
☐ Renal replacement therapy
☐ Invasive procedure
☐ Thrombocytopenia
☐ Use of thrombolysis
☐ Active bleeding
☐ Start of therapeutic anticoagulation, e.g. for VTE or atrial fibrillation
☐ Serious adverse reaction (e.g., LMWH-induced anaphylaxis or heparin-induced thrombocytopenia)
☐ Dose scheduled, but not administered because ICU admission occurred after, or ICU discharge occurred before, the scheduled dosing time
☐ Participation ended due to withdrawal of consent, discontinuation of active therapy, involuntary hospitalization, or a clinical decision
☐ Trial site not active in the thromboprophylaxis domain
☐ Dose adjustment (or temporary withholding of dose) for another reason

Conditions:

- Administered LMWH: Tinzaparin
- Deviation from the allocated dose: Yes

Administered dose tinzaparin [description]

Name: administered_dose_tinzaparin

Lifespan: 0 seconds

Minimum value: 2500

Maximum value: 40000

IU

Reason for deviation, one or more of the following [description]

Name: reason_for_deviation

Lifespan: 0 seconds

- ☐ Acute or chronic kidney injury
- ☐ Renal replacement therapy
- ☐ Invasive procedure
- ☐ Thrombocytopenia
- ☐ Use of thrombolysis
- ☐ Active bleeding
- ☐ Start of therapeutic anticoagulation, e.g. for VTE or atrial fibrillation
- ☐ Serious adverse reaction (e.g., LMWH-induced anaphylaxis or heparin-induced thrombocytopenia)
- ☐ Dose scheduled, but not administered because ICU admission occurred after, or ICU discharge occurred before, the scheduled dosing time
- ☐ Participation ended due to withdrawal of consent, discontinuation of active therapy, involuntary hospitalization, or a clinical decision
- ☐ Trial site not active in the thromboprophylaxis domain
- ☐ Dose adjustment (or temporary withholding of dose) for another reason

INCEPT-Thromboprophylaxis - dayform non-trial site 1-90

Form type: Non-trial site dayform

Follows clinical day: Yes

Timing: 1st, 2nd, 3rd, 4th, 5th, 6th, 7th, 8th, 9th, 10th, 11th, 12th, 13th, 14th, 15th, 16th, 17th, 18th, 19th, 20th, 21st, 22nd, 23rd, 24th, 25th, 26th,

27th, 28th, 29th, 30th, 31st, 32nd, 33rd, 34th, 35th, 36th, 37th, 38th, 39th, 40th, 41st, 42nd, 43rd, 44th, 45th, 46th, 47th, 48th, 49th, 50th, 51st, 52nd, 53rd, 54th, 55th, 56th, 57th, 58th, 59th, 60th, 61st, 62nd, 63rd, 64th, 65th, 66th, 67th, 68th, 69th, 70th, 71st, 72nd, 73rd, 74th, 75th, 76th, 77th, 78th, 79th, 80th, 81st, 82nd, 83rd, 84th, 85th, 86th, 87th, 88th, 89th, 90th day after Enrolment for INCEPT-Thromboprophylaxis

Span: 1 day

Location(s): Non-trial site

Serious adverse reactions and other relevant events

Venous thromboembolism on this day - composite [description]

Name: venous_thromboembolism_on_this_day_composite

Lifespan: 0 seconds

Conditions:

- Venous thromboembolism on this day: Yes

Type of venous tromboembolism - composite [description]

Name: type_of_tromboembolism_composite

Lifespan: 0 seconds

Conditions:

- Type of venous tromboembolism: Pulmonary embolism

The anatomical location of the pulmonary embolism [description]

Name: location_of_pe

Lifespan: 0 seconds

- ☐ Central artery
- ☐ Lobar artery
- ☐ Segmental artery
- ☐ Subsegmental artery

Presence of a central venous catheter [description]

Name: presence_of_a_central_venous_catheter

Lifespan: 0 seconds

- ○ Yes

○ No

The imaging modality used to detect the pulmonary embolism [description]

Name: imaging_modality_pe

Lifespan: 0 seconds

☐ CT angiography
☐ High probability ventilation-perfusion scan

Start of treatment with therapeutic dose anticoagulation < 24h after diagnosis [description]

Name: start_therapeutic_dose_anticoagulation_24h

Lifespan: 0 seconds

○ Yes
○ No

Conditions:

• Type of venous tromboembolism: Deep venous thrombosis

The anatomical location of the DVT [description]

Name: location_of_dvt

Lifespan: 0 seconds

☐ Iliac vein
☐ Femoral vein
☐ Popliteal vein
☐ Distal deep vein of the lower extremity
☐ Internal jugular vein
☐ Brachiocephalic vein
☐ Subclavian vein
☐ Axillary vein
☐ Distal deep vein of the upper extremity

Presence of a central venous catheter in the same vein as the DVT during the 24 hours before the event [description]

Name: presence_of_a_central_venous_catheter_in_relation_to_dvt

Lifespan: 0 seconds

○ Yes
○ No

The imaging modality used to detect the deep venous trombosis [description]

Name: imaging_modality_dvt

Lifespan: 0 seconds

☐ Point-of-care ultrasound
☐ Compression ultrasound
☐ Venography
☐ Computed tomography (CT)
☐ Magnetic resonance imaging (MRI)

The professional who performs the procedure that leads to the diagnosis [description]

Name: professional

Lifespan: 0 seconds

○ ICU professional
○ Radiology professional

Start of treatment with therapeutic dose anticoagulation < 24h after diagnosis [description]

Name: start_therapeutic_dose_anticoagulation_24h

Lifespan: 0 seconds

○ Yes
○ No

Major bleeding on this day - composite [description]

Name: major_bleeding_on_this_day_composite

Lifespan: 0 seconds

Conditions:

• Major bleeding on this day: Yes

Type of major bleeding - composite [description]

Name: type_of_major_bleeding_composite

Lifespan: 0 seconds

Conditions:

• Type of major bleeding: Symptomatic bleeding

Site of bleeding [description]

Name: site_of_bleeding

Lifespan: 0 seconds

- ☐ Intracranial
- ☐ Intraspinal
- ☐ Intraocular
- ☐ Retroperitoneal
- ☐ Intraarticular
- ☐ Pericardial
- ☐ Intramuscular with compartment syndrome

Conditions:

• Type of major bleeding: Bleeding that requires intervention

Type of intervention [description]

Name: type_of_intervention

Lifespan: 0 seconds

- ☐ Transfusion of ≥400ml whole blood or red cells
- ☐ Endoscopy
- ☐ Endovascular management
- ☐ Surgery

INCEPT-Thromboprophylaxis - followup (death)

Form type: 30/90/180 days followup

Follows clinical day: Yes

Timing: 180th day after Enrolment for INCEPT-Thromboprophylaxis

Span: 1 day

Location(s): Trial Site, Non-trial site, Out of hospital

Outcomes - other

Please confirm that the participant’s medical record has been assessed for death, and that the event has been entered in the event history if so [description]

Name: death_before_day_180

Lifespan: 0 seconds

- ○ Yes
- ○ Unknown

INCEPT-Thromboprophylaxis - screening

Form type: Screening

Follows clinical day: No

Timing: 0.0 seconds after Screening for INCEPT-Thromboprophylaxis

Span: 0 seconds

Location(s): Trial Site

Inclusion Criteria

Decision by the treating clinician to start thromboprophylaxis with LMWH, or to continue LMWH prophylaxis [description]

Name: decision_to_start_thromboprophylaxis

Lifespan: 0 seconds

- ○ Yes
- ○ No

Exclusion Criteria

Solid organ transplant during current hospital admission [description]

Name: solid_organ_transplant_during_current_hospital_admission

Lifespan: 0 seconds

- ○ Yes
- ○ No

Weight <40 kg [description]

Name: weight_below_40_kg

Lifespan: 0 seconds

- ○ Yes
- ○ No

Mechanical circulatory support (e.g., ECMO) [description]

Name: mechanical_circulatory_support

Lifespan: 0 seconds

- ○ Yes
- ○ No

More than one prophylactic dose of anticoagulation administered during current ICU stay, including ICU days in other hospitals [description]

Name: more_than_one_prophylactic_dose_of_anticoagulation_administered

Lifespan: 0 seconds

- ○ Yes
- ○ No

Known pregnancy [description]

Name: known_pregnancy

Lifespan: 0 seconds

- ○ Yes
- ○ No

Known or suspected previous adverse reaction to any type of heparin, including allergy and heparin-induced thrombocytopenia [description]

Name: allergy_heparin

Lifespan: 0 seconds

- ○ Yes
- ○ No

Inclusion in another interventional trial or INCEPT domain where co-enrolment with the INCEPT-Thromboprophylaxis domain is not permitted [description]

Name: inclusion_in_another_trial_where_coenrolment_with_incept_thromboprophylaxis_is_not_acceptable

Lifespan: 0 seconds

- ○ Yes
- ○ No

Stratification Variables

Site [description]

Name: site

Lifespan: 0 seconds

History of venous thromboembolism [description]

Name: history_of_vte

Lifespan: 0 seconds

- ○ Yes
- ○ No

Additional Variables

Presence of haematological or metastatic cancer [description]

Name: haematological_or_metastatic_cancer

Lifespan: 2 days

- ○ Yes
- ○ No

Date of birth [description]

Name: date_of_birth

Lifespan: 1 year

Minimum value: 115 years ago

Maximum value: 18 years ago

Plausible minimum: 100 years ago

Sex [description]

Name: sex

Lifespan: 1 year

- ○ Female
- ○ Male

Acute surgery within 7 days [description]

Name: acute_surgical_admission

Lifespan: 12 hours

- ○ Yes
- ○ No

Use of invasive mechanical ventilation at the time of randomisation [description]

Name: use_of_invasive_mechanical_ventilation_at_randomisation

Lifespan: 30 minutes

- ○ Yes
- ○ No

Use of circulatory support (infusion of vasopressor/inotropes) at randomisation [description]

Name: use_of_circulatory_support_at_randomisation

Lifespan: 0 seconds

- ○ Yes
- ○ No

Use of renal replacement therapy within the last 72 hours prior to randomisation [description]

Name: rrt_within_72h_before_randomisation

Lifespan: 0 seconds

- ○ Yes
- ○ No

Use of antiplatelet medication in the 24 hours preceding randomisation [description]

Name: use_of_antiplatelet_medication

Lifespan: 0 seconds

- ○ Yes
- ○ No

Presence of a central venous catheter [description]

Name: presence_of_a_central_venous_catheter

Lifespan: 0 seconds

- ○ Yes
- ○ No

Suspected sepsis [description]

Name: suspected_sepsis

Lifespan: 0 seconds

- ○ Yes
- ○ No

INCEPT-Thromboprophylaxis- 30/90 days followup

Form type: 30/90/180 days followup

Follows clinical day: No

Timing: 30.0, 90.0 days after Enrolment for INCEPT-Thromboprophylaxis

Span: 0 seconds

Location(s): Trial Site, Non-trial site, Out of hospital

Outcomes - other

Please confirm that the participant’s medical record has been assessed for death or any new admissions, and that any new events have been added to the event history. [description]

Name: 30_90_day_followup

Lifespan: 0 seconds

- ○ Yes
- ○ Unknown

Variable descriptions

Age ≥ 18 years

Age of the participant in whole years at enrolment should be 18 years or above. The
age of the participant will be calculated using the date of randomisation and the date of birth.

Acutely admitted to the ICU

This includes ICU admissions after emergency surgery, unplanned ICU admissions after elective surgery, and unplanned prolonged ICU admissions due to complications after elective surgery (i.e., admissions occurring or being prolonged due to an unexpected, worsened condition, but excluding planned ICU admissions after elective surgery without clinical deterioration).

Informed consent following inclusion expected to be unobtainable

Patients where the clinician or investigator expects to be unable to obtain the necessary consent following inclusion according to the national regulations.

Patient is under coercive measures

Patients with ongoing involuntary hospital admission or under the jurisdiction of correctional authorities.

Please confirm that the participant’s medical record has been assessed for death or any new admissions, and that any new events have been added to the event history.

No description

IV crystalloid volumes within the last 24 hours before enrolment

Total volume of IV crystalloids (i.e. saline, Ringer’s solutions, Harmann’s solution or PlasmalyteTM) administered to the patient in the 24 hours prior to randomisation.

Shock type - composite

No description

Lowest P-albumin within the last 24 hours prior to randomisation

Lowest registered plasma albumin measured in the 24 hours prior to randomisation

Major bleeding on this day - composite

No description

Severe anaphylactic reaction to albumin on this day

Anaphylactic reactions are defined as a urticarial skin reaction **AND** at least one of the following observed after randomisation in relation to the skin reaction:

- **Worsened circulation**: >20% decrease in blood pressure, new vasopressor infusion, or >20% increase in vasopressor dose.
- **Increased airway resistance**: >20% increase in the peak pressure on ventilation.
- **Clinical stridor or bronchospasm**.
- **Subsequent treatment with bronchodilators**.

Volume of albumin 5% (or lower concentration) on this day

No description

Volume of albumin 20% (or higher concentration) on this day

No description

Total volume of packed red blood cells on this day

No description

Total fluid input on this day

Sum of all fluids administered that day—intravenous, enteral, or other routes—as recorded in the fluid balance chart (**including albumin** and blood products). Include metabolic water if it is recorded at the site.

Total fluid balance on this day

Total fluid intake minus total fluid output as recorded in the fluid balance chart, including insensible components (e.g., metabolic water and insensible perspiration) where recorded at the site.

Protocol violation in the albumin domain on this day

Protocol Violation Definition

Albumin Use (Intervention)

No albumin given during resuscitation or as substitution in cases of suspected or overt albumin loss, or when P-albumin levels are ≤25 g/L.

No Albumin Use (Control)

Albumin given without one of the following extenuating circumstances occurring:

- Large volume ascites drainage
- Spontaneous bacterial peritonitis
- Hepatorenal syndrome

Please confirm that the participant’s medical record has been assessed for death, and that the event has been entered in the event history if so

No description

Site

This is a built-in variable that should not be modified or deleted.

Presence of haematological or metastatic cancer

Haematological malignancy includes any of the following:

- Leukaemia: Acute lymphoblastic leukaemia, acute myelogenous leukaemia, chronic myelogenous leukaemia, chronic lymphocytic leukaemia.
- Lymphoma: Hodgkin's disease, and Non-Hodgkin lymphoma (e.g., small lymphocytic lymphoma, diffuse large B-cell lymphoma, follicular lymphoma, and mantle cell lymphoma).
- Hairy cell leukaemia, marginal zone lymphoma, Burkitt's lymphoma, posttransplant lymphoproliferative disorder, T-cell prolymphocytic leukaemia, B-cell prolymphocytic leukaemia, Waldenström's macroglobulinemia, and other NK- or T-cell lymphomas.
- Multiple myeloma/plasma cell myeloma.

Metastatic cancer is defined as proven metastasis by surgery, computed tomography (CT) scan, or any other method.

Date of birth

No description

Sex

The sex of the participant assigned at birth (male or female).

Acute surgery within 7 days

Participants who have undergone any acute surgical procedure (i.e., surgery added to the operating room schedule 24 hours or less before surgery) during the current admission within 7 days prior to randomisation.

Use of invasive mechanical ventilation at the time of randomisation

Invasive mechanical ventilation: use of mechanical ventilation via a cuffed endotracheal
tube or tracheostomy.

Use of renal replacement therapy within the last 72 hours prior to randomisation

Use of any form of in-hospital renal replacement therapy (e.g., dialysis, hemofiltration, or
hemodiafiltration) at any rate within the last 72 hours prior to randomisation. We will not register
the use of dialysis at home.

Ongoing infusion of a vasopressor or inotropic agent

e.g., noradrenaline, adrenaline, vasopressin, phenylephrine, dopamine, dobutamine, milrinone, or levosimendan

Received albumin during the current ICU stay

Administration of albumin (any concentration and volume) during the current ICU stay

Is sepsis the primary cause of shock

Septic shock: Shock caused by severe infection.

Traumatic brain injury

Suspected or documented head trauma injury leading to brain damage .

Known pregnancy

*Note: The INCEPT-Albumin and INCEPT-Thromboprophylaxis protocols do **not** require a negative urine or plasma hCG test in all eligible fertile women.*

Known albumin allergy

No description

Plasma lactate ≥ 2 mmol/L in any blood sample performed within the last 3 hours

No description

Religious objection to administration of albumin

Patient or guardian refusal to receive albumin due to religious beliefs

Inclusion in another interventional trial or INCEPT domain where co-enrolment with the INCEPT-Albumin domain is not permitted.

No description

Lowest platelet count in the 24 hours prior to randomisation

No description

Venous thromboembolism on this day - composite

No description

Severe anaphylactic reaction to LMWH on this day

Anaphylactic reactions are defined as a urticarial skin reaction **AND** at least one of the following observed after randomisation in relation to the skin reaction:

- **Worsened circulation**: >20% decrease in blood pressure, new vasopressor infusion, or >20% increase in vasopressor dose.
- **Increased airway resistance**: >20% increase in the peak pressure on ventilation.
- **Clinical stridor or bronchospasm**.
- **Subsequent treatment with bronchodilators**.

Register **“Yes”** only on the **first day** the event occurs.
Do **not** select “Yes” on subsequent days unless a **new, separate event** begins — in that case, register “Yes” again on the **first day** of the new event.

Heparin induced thrombocytopenia (HIT) on this day

Testing for HIT in case of clinical suspicion will be left to the discretion of the treating physician.

Definite HIT
- Positive serotonin release assay (SRA) or equivalent functional HIT confirmatory test.

Possible HIT
- Positive enzyme-linked immunosorbent assay (ELISA) or quantitative rapid immunoassay **without** a functional HIT confirmatory test **and** study medication is stopped.

Register **“Yes”** only on the **first day** the event occurs.
Do **not** select “Yes” on subsequent days unless a **new, separate event** begins — in that case, register “Yes” again on the **first day** of the new event.

Administration of the site-preferred LMWH in the allocated dose on this day - composite

No description

History of venous thromboembolism

Documented medical history of pulmonary embolism and/or lower or upper extremity deep vein thrombosis.

Solid organ transplant during current hospital admission

No description

Weight <40 kg

Measured or estimated body weight <40 kg at the time of screening.

Mechanical circulatory support (e.g., ECMO)

Current application of central or peripheral extracorporeal membrane oxygenation devices (including veno-venous).

Use of circulatory support (infusion of vasopressor/inotropes) at randomisation

Continuous infusion (i.e., ≥1 hour) of any vasopressor/inotrope agent (i.e., norepinephrine, epinephrine, phenylephrine, vasopressin analogues, angiotensin, dopamine, dobutamine, milrinone, or levosimendan) at randomisation (excluding strictly procedure-related infusions).

Decision by the treating clinician to start thromboprophylaxis with LMWH, or to continue LMWH prophylaxis

No description

Use of antiplatelet medication in the 24 hours preceding randomisation

Use of acetylsalicylic acid, dipyridamole, clopidogrel, prasugrel, and/or ticagrelor in the 24 hours preceding randomisation.

More than one prophylactic dose of anticoagulation administered during current ICU stay, including ICU days in other hospitals

Administration of more than one prophylactic dose of LMWH, unfractionated heparin, pentasaccharides, or direct oral anticoagulants during current ICU stay. This includes ICU days in another ICU and/or hospital.

Presence of a central venous catheter

The presence of a **central venous catheter (CVC)** is defined as any venous catheter placed in the **internal jugular**, **subclavian**, or **femoral** vein, including **peripherally inserted central catheters (PICC)**. For baseline forms, the catheter must be in place **at the time of randomisation**.

Suspected sepsis

Suspected sepsis according to the Sepsis 3 criteria at the time of randomisation.

Sepsis-3 criteria
- **Sepsis:**
Requires **both**:
1) **Suspected or documented infection**, and
2) **Acute increase in SOFA ≥ 2 points** from baseline.
If baseline organ dysfunction/SOFA is unknown, assume baseline SOFA = 0.

- **Septic shock:**
Sepsis **and** **both** of the following:
1) **Vasopressors required** to maintain **MAP ≥ 65 mmHg**, and
2) **Serum lactate > 2 mmol/L** *despite adequate fluid resuscitation*.

Known or suspected previous adverse reaction to any type of heparin, including allergy and heparin-induced thrombocytopenia

Documented allergic reaction to **heparin**, including:
- **Type I** reactions — angioedema, bronchospasm, generalised urticaria, anaphylaxis
- **Type III** reactions — injection-site edema, inflammation, induration
- **Type IV** reactions — plaques and pruritic eczemas at the injection site
- **And/or** documented history of heparin-induced thrombocytopenia

Inclusion in another interventional trial or INCEPT domain where co-enrolment with the INCEPT-Thromboprophylaxis domain is not permitted

Documented inclusion in a trial/domain where it is known that co-enrolment in INCEPT-Thromboprophylaxis is not permitted (after a formal evaluation).