INCEPT

The Intensive Care Platform Trial

Educational material for nurses

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INCEPT
The Intensive Care Platform Trial


CRIC
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in Intensive Care


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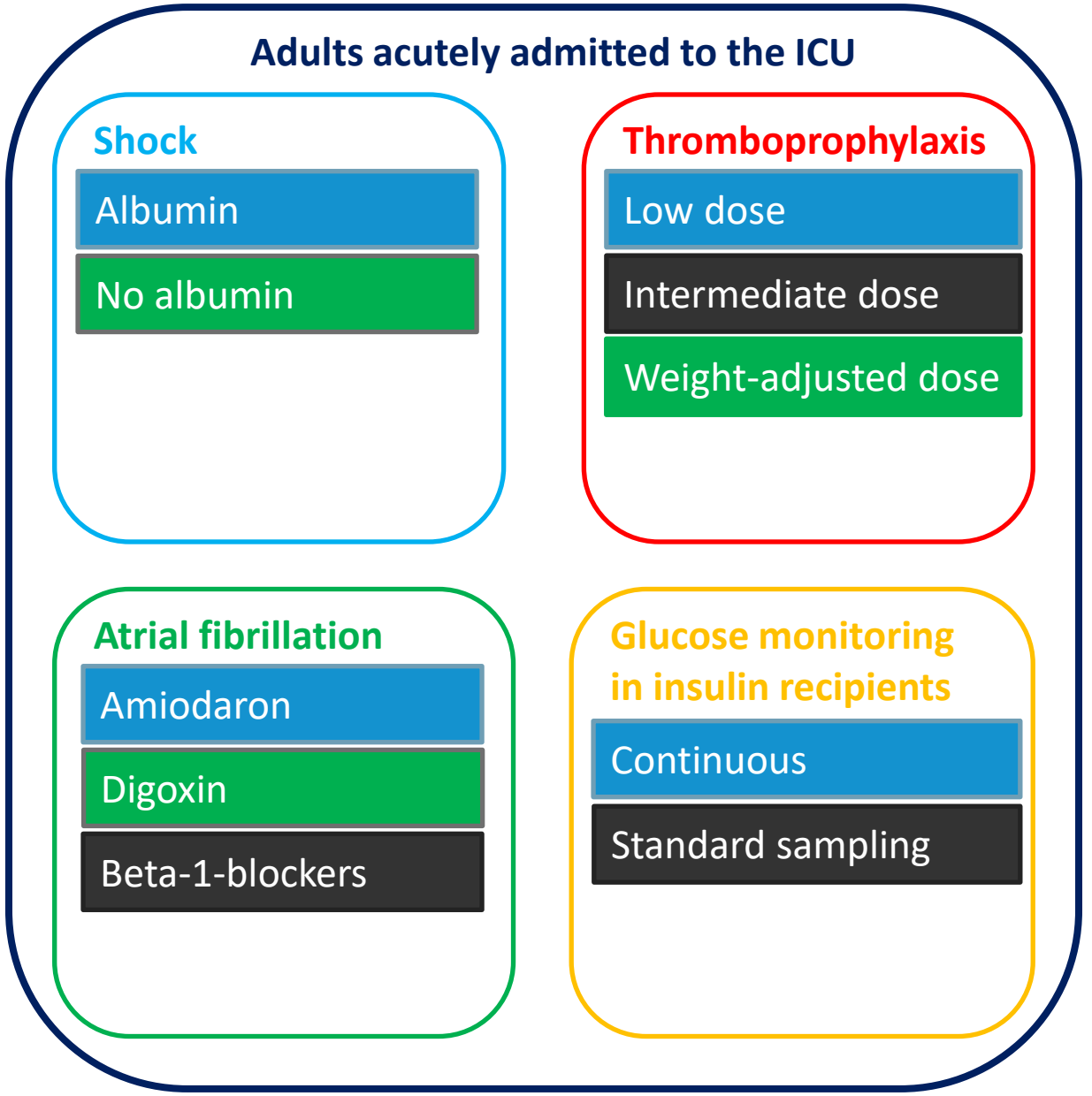
Platform trial



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Population

Inclusion criteria

- Adults acutely admitted to the ICU
- Eligible for at least one active domain

Exclusion criteria

- Informed consent after inclusion expected to be unobtainable
- Admitted under coercive measures

INCEPT-Albumin

Albumin versus no albumin in shock

Albumin

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DOI: 10.1111/aas.14479

RESEARCH ARTICLE

acta Anaesthesiologica Scandinavica

Preferences for albumin use in adult intensive care unit patients with shock: An international survey

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[Correction added on 19 November 2024, after first online publication: The Collaborator Group was added in the author byline.]

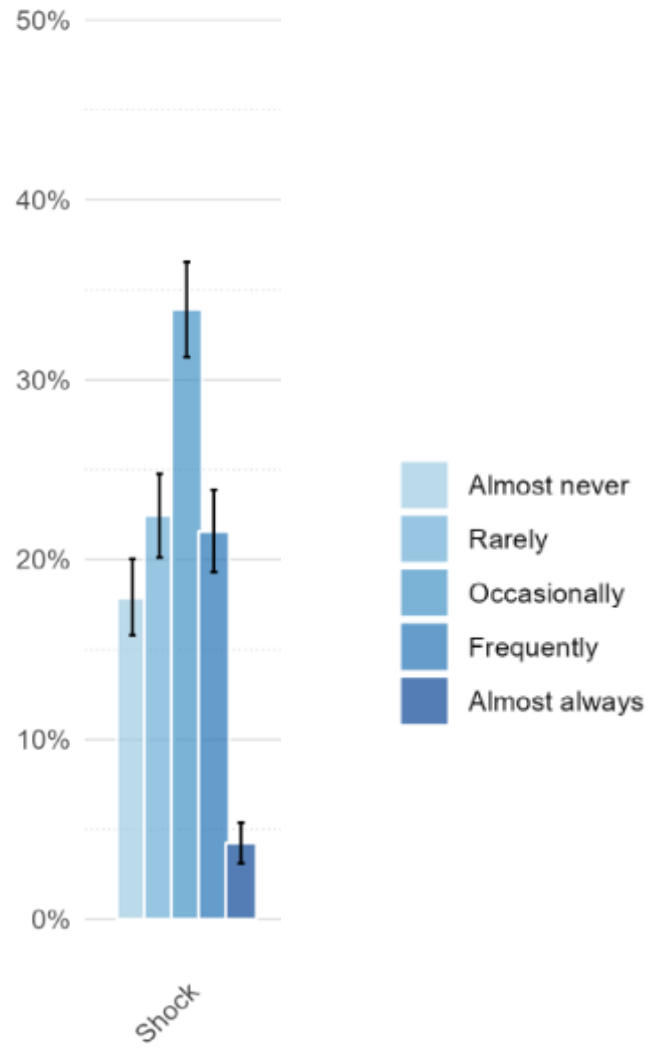
Abstract

Introduction: Use of albumin is suggested for some patients with shock, but preferences for its use may vary among intensive care unit (ICU) physicians.

Methods: We conducted an international online survey of ICU physicians with 20 questions about their use of albumin and their opinion towards a randomised trial among adults with shock comparing the use versus no use of albumin.

Results: A total of 1248 respondents participated, with a mean response rate of 37%, ranging from 18% to 75% across 21 countries. Respondents mainly worked in mixed ICUs and 92% were specialists in intensive care medicine. The reported use of albumin in general shock varied as 18% reported 'almost never', 22% 'rarely', 34% 'occasionally', 22% 'frequently' and 4% 'almost always' using albumin. In septic shock, 19% reported 'almost never', 22% 'rarely', 29% 'occasionally', 22% 'frequently' and 7% 'almost always' using albumin. Physicians' preferences were more consistent for haemorrhagic- and cardiogenic shock, with more than 45% reporting 'almost never' using albumin. While the reported use of albumin for other purposes than resuscitation was infrequent (40%–85% reported 'almost never' for five other indications), the most frequent other indications were low serum albumin levels and improvement

For affiliations refer to page 1241

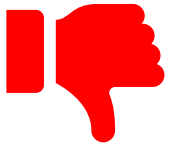


Sivapalan et al. 2024, doi: 10.1111/aas.14479

Albumin

Alive and without life-support?

Improved hemodynamics?
Less fluid use?



Kidney failure?
Coagulopathy?

Albumin

Inclusion criteria

- Shock
  - Ongoing infusion of vasopressor/inotrope AND
  - Plasma lactate ≥2 mmol/L within the last 3 hours
- Both interventions considered clinically appropriate

  (to use albumin or not)

Albumin

Exclusion criteria

- Traumatic brain injury
- Use of albumin during current ICU stay
- Known pregnancy
- Religious objection towards albumin
- Known albumin allergy
- Inclusion in another trial or INCEPT domain where co-enrolment with INCEPT-Albumin is not permitted

Albumin Intervention vs comparator

- During circulatory failure in addition to crystalloid (resuscitation)
- Substitution in case of:
  - Suspected/overt albumin loss
  - P-albumin ≤25 g/L

vs

Albumin may be considered if the following special circumstances occur:

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

Timing, volume and concentration at clinician's discretion

P-albumin measured according to usual practice

Outcomes

Primary: Days alive without life-support at 30 days

Secondary:
INCEPT core outcomes

- All-cause mortality at 30, 90, and 180 days
- Days alive without life support at 90 days
- Days alive and out of hospital at 30 and 90 days
- Days free of delirium at 30 days
- Health-related quality of life (EQ-5D-5L and EQ-VAS) at 180 days
- Cognitive function (MiniMoCA) at 180 days
- Domain specific safety outcomes (anaphylaxis and major bleeding) at 30 and 90 days

INCEPT-Thromboprophylaxis

Low versus intermediate versus weight-adjusted LMWH dose

novo nordisk foundation

University Medical Center Groningen

RHS Rigshospitalet Copenhagen University Hospital

CRIC Collaboration for Research in Intensive Care

Thromboprophylaxis

OPEN ACCESS

Check for updates

Anticoagulants for thrombosis prophylaxis in acutely ill patients admitted to hospital: systematic review and network meta-analysis

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Additional material is published online only. To view please visit the journal online.

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Accepted: 21 May 2022

ABSTRACT

OBJECTIVE
To assess the benefits and harms of different types and doses of anticoagulant drugs for the prevention of venous thromboembolism in patients who are acutely ill and admitted to hospital.

DESIGN
Systematic review and network meta-analysis.

DATA SOURCES
Cochrane CENTRAL, PubMed/Medline, Embase, Web of Science, clinical trial registries, and national health authority databases. The search was last updated on 16 November 2021.

ELIGIBILITY CRITERIA FOR SELECTING STUDIES
Published and unpublished randomised controlled trials that evaluated low or intermediate dose low-molecular-weight heparin, low or intermediate dose unfractionated heparin, direct oral anticoagulants, pentasaccharides, placebo, or no intervention for the prevention of venous thromboembolism in acutely ill adult patients in hospital.

MAIN OUTCOME MEASURES
Random effects, bayesian network meta-analyses used four co-primary outcomes: all cause mortality, symptomatic venous thromboembolism, major bleeding, and serious adverse events at or closest timing to 90 days. Risk of bias was also assessed using the Cochrane risk-of-bias 2.0 tool. The quality of evidence was graded using the Confidence in Network Meta-Analysis framework.

RESULTS
44 randomised controlled trials that randomly assigned 90 095 participants were included in the main analysis. Evidence of low to moderate quality suggested none of the interventions reduced all cause mortality compared with placebo. Pentasaccharides (odds ratio 0.32, 95% credible interval 0.08 to 1.07), intermediate dose low-molecular-weight heparin (0.66, 0.46 to 0.93), direct oral anticoagulants (0.68, 0.33 to 1.34), and intermediate dose unfractionated heparin (0.71, 0.43 to 1.19) were most likely to reduce symptomatic venous thromboembolism (very low to low quality evidence). Intermediate dose unfractionated heparin (2.63, 1.00 to 6.21) and direct oral anticoagulants (2.31, 0.82 to 6.47) were most likely to increase major bleeding (low to moderate quality evidence). No conclusive differences were noted between interventions regarding serious adverse events (very low to low quality evidence). When compared with no intervention instead of placebo, all active interventions did more favourably with regard to risk of venous thromboembolism and mortality, and less favourably with regard to risk of major bleeding. The results were robust in prespecified sensitivity and subgroup analyses.

CONCLUSIONS
Low-molecular-weight heparin in an intermediate dose appears to confer the best balance of benefits and harms for prevention of venous thromboembolism. Unfractionated heparin, in particular the intermediate dose, and direct oral anticoagulants had the least favourable profile. A systematic discrepancy was noted in intervention effects that depended on whether placebo or no intervention was the reference treatment. Main limitations of this study include the quality of the evidence, which was generally low to moderate due to imprecision and within-study bias, and statistical inconsistency, which was addressed post hoc.

SYSTEMATIC REVIEW REGISTRATION
PROSPERO CRD42020173088.

WHAT IS ALREADY KNOWN ON THIS TOPIC

The optimal anticoagulant type and dose for the prevention of venous thromboembolism in acutely ill adults in hospital is unknown

Previous pairwise meta-analyses have had a limited number of direct comparisons between different anticoagulant drugs and doses

WHAT THIS STUDY ADDS

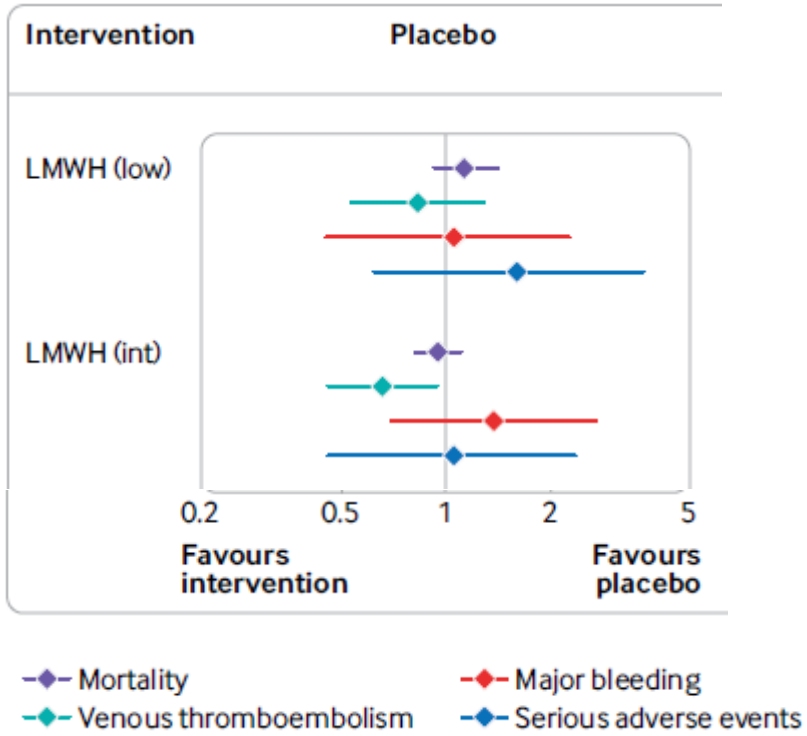
Low-molecular-weight heparin in an intermediate dose might confer the best balance between benefits and harms for prevention of venous thromboembolism; other anticoagulant types and doses had smaller thromboembolism reductions or an increased bleeding risk

A systematic discrepancy was noted in intervention effects that depended on whether placebo or no intervention was the reference treatment; future network meta-analyses should consider separating placebo and no intervention arms

The main limitations of this study were the quality of the evidence, which was generally low to moderate, and statistical inconsistency, which was dealt with post hoc

Introduction

Venous thromboembolism is a multifactorial disease frequently complicating the course of acute illness.[1] Up to half of all thrombotic events have been estimated to be attributable to a current or recent hospitalisation, making prevention of in-hospital venous thromboembolism a worthwhile aim.[2] Any anticoagulant intervention such as coumarin, unfractionated heparin, low-molecular-weight heparin, pentasaccharides, or direct oral anticoagulants can be



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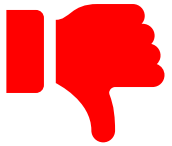
Alive and out of hospital?

Low versus intermediate versus weight-adjusted dose

Improved thromboprophylaxis?



More bleeding?

Thromboprophylaxis

Inclusion criteria

- Decision by treating clinician to start/continue thromboprophylaxis with LMWH
- All interventions considered clinically appropriate
  (low versus intermediate versus weight-adjusted dose)

- ICUs with systematic screening for deep vein thrombosis (DVT) cannot participate in domain

Exclusion criteria

- More than one prophylactic dose of anticoagulation during current ICU stay (including days in another ICU)
- Known/suspected previous adverse reactions to heparin (including allergy and heparin-induced thrombocytopenia)
- Known pregnancy
- Mechanical circulatory support
- Solid organ transplant during current hospital admission
- Weight < 40 kg
- Inclusion in another trial or INCEPT domain where co-enrolment with INCEPT-Thromboprophylaxis is not permitted

Intervention

Each ICU chooses one LMWH for everyone

(Dalteparin, enoxaparin, tinzaparin or nadroparin)

Shelf medication

Low versus intermediate versus weight-adjusted LMWH prophylaxis in ICU for max 90 days

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Thromboprophylaxis

Intervention

Site preferred LMWH Intervention	Weight (kg)*	Enoxaparin dose (mg)	Tinzaparin dose (IE)	Dalteparin dose (IE)	Nadroparin dose (IE)
Fixed low dose	All	40	2500	2500	2850
Fixed intermediate dose	All	60	4500	5000	5700
Weight-adjusted dose	≥40 - 50	40	2500	2500	2850
	≥50 - 60	40	2500	2500	3800
	≥60 - 70	40	4500	5000	3800
	≥70 - 80	60	4500	5000	3800
	≥80 - 90	60	4500	5000	5700
	≥90 - 100	80	7000	7500	5700
	≥100 - 110	80	7000	7500	7600
	≥110 - 120	80	8000	7500	7600
	≥120	100	8000	10000	7600

*Actual body weight as estimated or measured at time of screening

Thromboprophylaxis

Intervention

Dose adjustment or pausing of the intervention at clinician's discretion when …

- Acute and/or chronic kidney injury
- Renal replacement therapy
- Thrombocytopenia
- Invasive procedures
- Use of thrombolysis
- Active (major) bleeding

Suggested triggers and dose adjustment strategies available in domain-specific appendix and patient folder

Intervention

Intervention should stop permanently when…

- Therapeutic anticoagulation (e.g., treatment of VTE or atrial fibrillation)
- Serious adverse reaction (anaphylaxis or heparin-induced thrombocytopenia)

Other deviations from the allocated intervention will be considered a protocol violation

Outcomes

Primary: Days alive and out of hospital at 30 days

Secondary:

INCEPT core outcomes

- All-cause mortality at 30, 90, and 180 days
- Days alive without life support at 30 and 90 days
- Days alive and out of hospital at 90 days
- Days free of delirium at 30 days
- Health-related quality of life (EQ-5D-5L and EQ-VAS) at 180 days
- Cognitive function (Mini-MoCA) at 180 days

Domain specific secondary outcomes

- Venous thromboembolism (DVT or pulmonary embolism) at 30 and 90 days
- Major bleeding at 30 and 90 days
- Domain specific safety outcomes (anaphylaxis and heparin-induced thrombocytopenia) at 30 and 90 days

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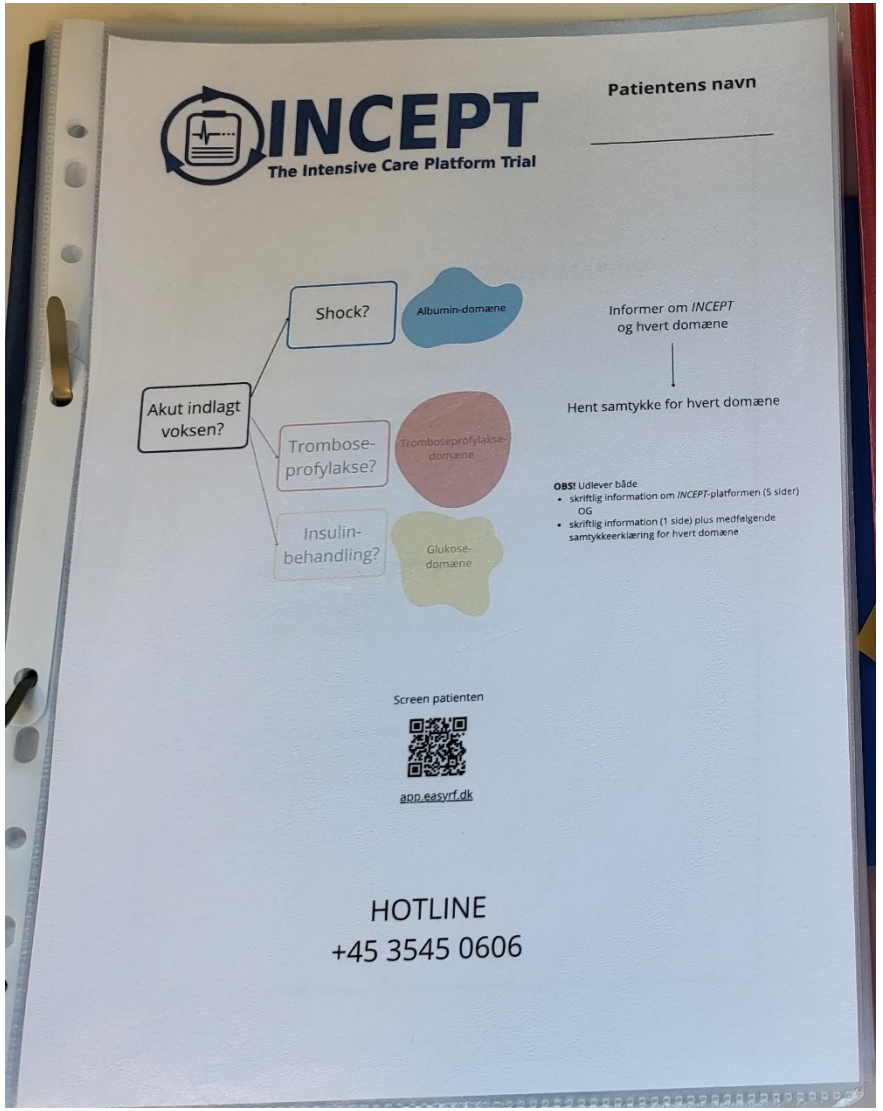
Questions?

Workflow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Patientens navn
Shock?
Albumin-domæne
Akut indlagt voksen?
Trombose-profylakse?
Trombose-profylakse-domæne
Insulin-behandling?
Glukose-domæne
Informer om INCEPT og hvert domæne
Hent samtykke for hvert domæne
OBS! Udlever både
skriftlig information om INCEPT-platformen (5 sider) OG
skriftlig information (1 side) plus medfølgende samtykkeerklæring for hvert domæne
Screen patienten
app.easyrf.dk
HOTLINE
+45 3545 0606

After randomisation

The enrolling physician:

- Inform the clinical staff
- Update relevant medication orders
- Write an inclusion note in the patient record
- Inform the patient's proxies as soon as possible in order to obtain consent

Before/after randomisation

For nurses:

- Check whether your patient is a trial participant
- If albumin is considered or patient is to be fluid resuscitated – consider whether the patient may be eligible for the albumin domain
- Follow the prescriptions
- Approachable and responsive to relatives – reach out to research staff if in doubt.
- If you have questions – use the hotline +45 3545 0606

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Question?