

INCEPT-Thromboprophylaxis for the patient

Background

About one out of 10 intensive care unit (ICU) patients develop a blood clot (thrombosis). Blood clots usually develop in the legs, which is a serious complication. The blood clot can break off and travel to the lungs, which can be life-threatening. It is recommended that ICU patients get preventive treatment (called prophylaxis) with blood-thinning drugs called low-molecular-weight heparin to reduce the risk of blood clots. Conversely, one out of 10 to 20 ICU patients will develop bleeding. Using blood-thinners is a balancing act, because blood-thinners increase the risk of bleeding. The optimal doses should be just high enough to prevent blood clots, but not so high that bleeding occurs. We are uncertain about the optimal dose of blood-thinners in ICU patients, and the used doses vary.

Purpose of *INCEPT-Thromboprophylaxis*

The purpose of the *INCEPT-Thromboprophylaxis* sub-trial (domain) is to compare the effect of three different doses of blood-thinners for ICU patients.

Which treatments do we investigate

You have either received the blood-thinner either in 1) a fixed low dose, 2) a fixed intermediate dose, or 3) a dose adjusted according to your weight. You received the treatment while you were in the ICU. We assess the effects and safety as described in the general information materials, with specific focus on blood clots and bleeding. No additional tests or procedures are performed.

Potential adverse reactions, risks and complications

Blood-thinners are used very frequently in the ICU in the same doses as used in the trial and are therefore familiar to caregivers. Common adverse reactions are bleeding and injection site reactions. Very rarely, serious allergies or a drop in the number of platelets (small cells that help control bleeding) occur. Other unexpected adverse reactions or complications may occur, but it is very unlikely. Should this happen, you will receive the necessary treatment.

Timeline and funding

The sub-trial will run until firm conclusions can be drawn. As such, the end date is not known, but it will most likely be in the year 2028. Funding is part of the *INCEPT*-grant.