Veiligheid en werkzaamheid van nadroparine in neonaten. een observationele studie

Geen registraties gevonden.

Ethische beoordeling	Goedgekeurd WMO
Status	Werving nog niet gestart
Type aandoening	Stollingsstoornissen en bloedingsdiathesen (excl. trombocytopenische)
Onderzoekstype	Observationeel onderzoek, met invasieve metingen

Samenvatting

ID

NL-OMON56793

Bron
ToetsingOnline

Verkorte titel
SAFE-NEO

Aandoening

- Stollingsstoornissen en bloedingsdiathesen (excl. trombocytopenische)
- Neonatale en perinatale aandoeningen

Synoniemen aandoening
bloedstolsel, Trombose

Betreft onderzoek met
Mensen

Ondersteuning

Primaire sponsor: Amsterdam UMC
Overige ondersteuning: Trombosestichting Nederland

Onderzoeksproduct en/of interventie

Trefwoord: Bloeding, nadroparine, neonaten, Werkzaamheid

Uitkomstmaten

Primaire uitkomstmaten

Therapeutisch nadroparine:

Evidence based doseringen van nadroparine voor extreem premature, premature en a terme neonaten door het PK/PD profiel te objectiveren tijdens de huidige standaardbehandeling

Profylactisch nadroparine:

Evidence based doseringen van nadroparine voor premature en a terme neonaten door het PK/PD profiel te objectiveren tijdens de huidige standaardbehandeling

Secundaire uitkomstmaten

Therapeutisch nadroparine:

-De incidentie van complete trombusresolutie in relatie tot antiXa spiegel binnen 3 maanden na start van nadroparinebehandeling

-De incidentie bloedingen in relatie tot anti-Xa spiegel binnen 3 maanden na start van nadroparinebehandeling tot 24 uur na stop nadroparine behandeling

Profylactisch nadroparine:

-De incidentie van een nieuwe of recidieftrombose in relatie tot anti-Xa spiegel binnen 3 maanden na start van nadroparinebehandeling

-De incidentie bloedingen in relatie tot anti-Xa spiegel na start van

nadroparinebehandeling tot 24 uur na stop nadroparine behandeling

Toelichting onderzoek

Achtergrond van het onderzoek

The incidence of venous thrombosis is rising rapidly in neonates.[1,2] This rise is the result of improved neonatal care over the past 20 years resulting in an increase in the survival of (extremely) premature and critically ill infants. When a venous thrombus occurs there is an indication for therapeutic anticoagulant treatment (anti Xa levels 0.5-1.0 IU/mL). Inhibition of the coagulation system gives the opportunity to resolve the clot. If neonates are at high risk for venous thrombosis preventive measures can be taken by prophylactic anticoagulant treatment (anti-Xa levels 0.1-0.4 IU/mL). This inhibits the coagulation system in a lesser way compared to therapeutic anticoagulant treatment and prevents formation of a thrombus.
In the Netherlands each year 250 neonates receive off-label therapeutic and prophylactic nadroparin treatment, without any information on the pharmacokinetics/-dynamics (PK/PD) and therefore optimal and safe dosage regimen. As a result, these neonates are prone to suboptimal treatment with a risk for thrombosis, a lack of thrombus resolution or major bleeding.
Therefore we designed an observational study during standard care to objectify the PK/PD in neonates.

Doel van het onderzoek

Therapeutic nadroparin administration:
Primary objective:
To develop evidence-based dosing regimens of nadroparin for extremely premature, premature and term neonates by means of the objectification of the PK/PD of nadroparin.
Secondary objective:
1) Investigate the relation between anti Xa levels and thrombus resolution within 3 months after the start of nadroparin treatment
Investigate the relation between anti Xa levels and bleeding during treatment with nadroparin until 24 hours after termination of nadroparin
Prophylactic nadroparin administration:
Primary objective:
To develop evidence-based dosing regimens of nadroparin for premature and term neonates by means of the objectification of the PK/PD of nadroparin.
Secondary objective:
1) Investigate the relation between anti Xa levels and new or recurrent

thrombosis during treatment with nadroparin

Onderzoeksopzet

A national observational prospective study, conducted in 6 Neonatal Intensive Care Units/ Children*s Hospitals in the Netherlands.

Inschatting van belasting en risico

As mentioned above, each year 250 neonates receive off label nadroparin treatment without any information on PK/PD and therefore optimal and safe therapeutic or prophylactic dosage regimen. Despite this off label treatment, dosage recommendations have been provided. As a result, these neonates are prone to suboptimal treatment with a risk of a new thrombosis, a lack of thrombus resolution, or major bleeding. This bleeding has an impact on the morbidity and survival of neonates Therefore we will perform an observational study during standard care to objectify the PK/PD in neonates. With the development of evidence-based therapeutic dosing regimens for extremely premature, premature and term neonates, and evidence-based prophylactic dosing regimens for premature and term neonates for nadroparin we can ensure these vulnerable neonates an effective treatment without toxicity, and therefore less complications. A possible risk is reducing the circulating blood volume of neonates by taking blood. Therefore we minimized the volume blood samples (5 mL in total per neonate). To avoid the burden of venepunctures we aim to include mainly neonates with central venous or arterial access and combine blood samples with standard blood samples.

Contactpersonen

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Wetenschappelijk

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Locaties

Landen waar het onderzoek wordt uitgevoerd

Netherlands

Deelname eisen

Leeftijd
Pasgeborenen
Prematuren (< 37 weken zwangerschap)

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Neonates already receiving therapeutic or prophylactic nadroparin dosage as part of their treatment.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

•No informed consent
•Major congenital malformations
•Metabolic disorders
•Previous cerebral bleeding
•Neonates with any condition that, as judged by the investigator, would place the neonate at increased risk of harm if he/she participated in the study.

Onderzoeksopzet

Opzet

Type: Observationeel onderzoek, met invasieve metingen

Blindering:	Open / niet geblindeerd
Controle:	Geen controle groep
Doel:	Behandeling / therapie

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-05-2024
Aantal proefpersonen:	75
Type:	Verwachte startdatum

Ethische beoordeling

Goedgekeurd WMO

Datum:	24-05-2024
Soort:	Eerste indiening
Toetsingscommissie:	METC Amsterdam UMC

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
CCMO	NL84834.018.24