Central Line-associated Bloodstream Infection Prevention Using TauroLock-Hep100 in Pediatric Oncology Patients

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A decrease in the incidence of central line-associated bloodstream infections in the investigational study group, compared to the control group.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bacterial infectious disorders
Study type	Interventional

Summary

ID

NL-OMON20136

Source
Nationaal Trial Register

Brief title
CATERPILLAR

Condition

- Bacterial infectious disorders

Health condition

Central line associated bloodstream infection Central venous thrombosis Pediatric oncology

Research involving
Human

Sponsors and support

Primary sponsor: KWF
Source(s) of monetary or material Support: Koningin Wilhelmina Fonds (KWF)

Kankerbestrijding

Intervention

- Medical device

Explanation

Outcome measures

Primary outcome

Incidence of first central line associated bloodstream infection

Secondary outcome

Time to first tunneled Central Line Associated Bloodstream Infection (CLABSI) since the insertion of the Central Venous Access Device (CVAD) CLABSI incidence per 1,000 CVAD-days Incidence of (a)symptomatic Central Venous Thromboses (CVTs) Incidence of bacteremia Dispense of thrombolysis/systemic antibiotic treatment due to CLABSIs/CVTs Incidence of and reasons for CVAD-removal Cultured microorganisms causing CLABSIs Days of hospital admission due to CLABSIs/CVTs Safety of the study locks in terms of known side effects, liver enzymes, severe adverse events (SAEs), intensive care unit admission, and mortality rate due to CLABSIs/CVTs

Study description

Background summary

Tunneled central venous access devices (CVAD) are fundamental in pediatric oncology for long-term venous access. The incidence of central line-associated bloodstream infections (CLABSI) is high. In the Princess Máxima Center, the incidence rate of CLABSI is 1.51 per 1,000 CVAD-days, CLABSIs are seen in at least 30% of the children with a CVAD, 17% of the inserted CVADs are removed early and 5% of the patients are admitted at an intensive care unit due to CLABSIs. Central venous thrombosis (CVT) is another severe complication of a CVAD, with an incidence rate of 0.02-0.24 per 1,000 CVAD-days. After a review of the literature, we concluded that the taurolidine-citrate(-heparin) lock solution (TCHL) is the most promising method for the prevention of CLABSIs and CVTs. In the Netherlands, the heparin lock (HL) is the standard of care. The HL however, does not have an antimicrobial activity and its use is barely supported by literature. The TCHL has anticoagulant and antimicrobial activities without reported resistance to taurolidine. The TCHL has shown to decrease the CVAD-infection incidence by 27-100% in hemodialysis, total parenteral nutrition, and adult oncology patients. In pediatric oncology patients, six studies have been performed. Unfortunately, these studies did not deliver enough evidence to implement the TCHL in

pediatric oncology patients, mainly due to the small study groups, n-total ≤ 180. Therefore, we want to perform an open labelled RCT in a large patient group (n=462) so that we can finally draw conclusions on the efficacy and safety of the TCHL in pediatric oncology patients. Our goal is to increase the quality of life for children with cancer by reducing the CLABSI-rate, CVAD-removal rate, dispense of antibiotics, days of hospital/intensive care admission, and mortality rate due to CLABSI.

Study objective

A decrease in the incidence of central line-associated bloodstream infections in the investigational study group, compared to the control group.

Study design

Every CVAD will be followed up until first tunneled CLABSI episode has been resolved (symptom free and/or negative blood cultures), removal of the CVAD, or death of the patient, whatever end-point will come first with a maximum study period of 90 days.

Intervention

Patients in the taurolidine, citrate and heparin lock study arm will receive a lock solution containing taurolidine 1.35%, citrate 4% and heparin 100 IU/ml (TauroLock™-Hep100). Patients in the heparin lock study arm will receive a lock solution containing the standard of care heparin 100 IU/ml. The lock volume will depend on the central venous access device type, the central venous access device (CVAD) lumen needs to be filled completely. The locks will be instilled with a minimum of once every three weeks, and a maximum of once every week. The study locks will be aspirated before manipulation of the CVAD.

Contacts

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Eligibility criteria

Age
Newborns
Newborns
Babies and toddlers (28 days-23 months)
Babies and toddlers (28 days-23 months)
Children (2-11 years)
Children (2-11 years)
Adolescents (12-15 years)
Adolescents (12-15 years)
Adolescents (16-17 years)
Adolescents (16-17 years)

Inclusion criteria

Age between 0 - <19 years

Radiological, cytological or histological proven paediatric malignancy (hematologic, solid, and neurologic malignancies)

Tunnelled external central venous access device or totally implantable venous access port to be inserted at the Princess Máxima Center for Pediatric Oncology

Planned central venous access device insertion of >90 days

Written consent signed according to local law and regulations

Parents/guardians or patient are willing and able to comply with the trial procedure

Exclusion criteria

A previous central venous access device removed < 12 months ago.

Expected treatment for a majority of the follow-up time in a different hospital than the Princess Maxima Center for pediatric oncology in the first 90 days of inclusion resulting in difficulties/the inability to visit the Princess Maxima Center at least once every 3 weeks.

Primary immunological disorder

Contra indications: known hypersensitivity to taurolidine, citrate or heparin, and a history of heparin-induced thrombocytopenia.

Documented bacteremia in the period from 24h before catheter insertion until inclusion

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-10-2020
Enrollment:	462
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Approved WMO

Date:	07-09-2017
Application type:	First submission
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

ID: 55586
Bron: ToetsingOnline

Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6500
NTR-old	NTR6688
CCMO	NL67388.041.20
ClinicalTrials.gov	NCT05740150
OMON	NL-OMON55586

Study results