The Aristocaths study

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N/A

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22330

Bron
NTR

Verkorte titel
N/A

Aandoening

aristocaths, catheter infections, catheter infecties, Ethanol lock solution, paediatric oncology patients

Ondersteuning

Primaire sponsor: Academic Medical Center, Amsterdam
Overige ondersteuning: Dutch Childhood Oncology Group, The Hague

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

First endpoint:
All patients will be prospectively followed till time of first documented catheter related infection, till death, or till removal of the catheter, whatever endpoint will come first. Maximum duration of the study 6 months.

Secondary endpoint:
Occurence of fever (with or without neutropenia), occurence of thrombosis (clinical or subclinical days of hospital admission, clinical sverity of the infection, outcome.

Toelichting onderzoek

Achtergrond van het onderzoek

Background

The use of tunnelled central venous catheters has many advantages in the treatment of children with cancer. However, especially in children with long neutropenic episodes, the risk of infection and subsequently venous thrombosis is present, which can lead to severe morbidity.

Objective of the study

To evaluate the efficacy and safety of ethanol lock solution for prevention of catheter-related infections in children treated for cancer compared to standard heparin solution.

Study design

Multicentre randomised controlled trial in paediatric oncology patients ages 1-18 years in whom a tunnelled central venous catheter will be inserted.

Intervention: After insertion of the catheter an ethanol (70%)-lock solution will be administered (3 mls) for a duration of 2 hours, once weekly or longer if the catheter is not locked in between. The control-group will be locked with the standard heparin (100U/ml) solution (3 mls).

The primary outcome measure will be the first catheter-related bacteraemia, death of the patient, or removal of the catheter, whatever comes first. As secondary outcome measures fever, antibiotic use, days of hospital admission and the presence of thrombosis will be evaluated. For each patient, the maximim duration of the study will be 6 months.

Poweranalysis: To reduce the catheter related infection rate from 30% to 15%, 300 tunnelled catheters are needed in both arms with 85% of detecting a difference.

Clinical/scientific relevance

If ethanol lock solution will decrease the number of infections and thrombosis, this will lead to a reduction in morbidity and mortality due to infections, and less postponement of chemotherapeutic treatment with ultimate higher survival. Ethanol lock solutions will be used routinely in all pediatric cancer centres in the Netherlands and possibly international.

Doel van het onderzoek

N/A

Onderzoeksopzet

Interim analyses: 1,5 year after start study!

Onderzoeksproduct en/of interventie

Central randomisation will be performed, allocating the patients to the control or experimental group. Both the patient and the investigators will be blinded tot the treatment.

The experimental group: Ethanol 70%-ARM
For patients who are randomized to the ethanol 70% arm, the lock solution will consist of 3 ml of 70% ethanol. A volume of 3 ml of ethanol will be used to fill the catheter and will be locked in place for 2 hours. If the child receives a baby port the the lock solution will only be 1.5 mls for 2 hours. This will be repeated once weekly (range 5-10 days). If the child has a port a cath and does not need treatment within one week then it is allowed to extend the lock procedure. If the child has a double lumen Broviac inserted the lock solution per catheter will be 1.5 mls. After 2 hours the lock solution will be flushed with 3 ml of normal saline and 3 mls standard heparin will be used to close the catheter.. If the catheter needs to be used in between, the standard procedure will be followed: flushing the catheter with 3 ml of heparin

The control group: Heparin 100 U/ml- ARM
For patients who are randomized to the standard heparin 100 U/ml-arm, the lock solution will consist of 3 ml of heparin 100 U/ml. A volume of 3 ml will be used to fill each catheter and will be locked in place for 2 hours. If the child receives a baby port the lock solution will only be 1.5 mls for 2 hours. This will be repeated once weekly (range 5-10 days). If the child has a port a cath and does not need treatment within one week then it is allowed to extend the lock procedure. If the child has a double lumen Broviac inserted the lock solution per catheter will be 1.5 mls. After 2 hours the lock solution will be flushed with 3 ml of normal saline and 3 mls standard heparin will be used to close the catheter. If the catheter needs to be used in between, the standard procedure will be followed: flushing the catheter with 3 ml of heparin 100U/ml.

Contactpersonen

Publiek

TNO Quality of Life,
P.O. Box 2215
K.M. Pal, van der-de Bruin
Leiden 2301 CE
The Netherlands
+31 (0)71 5181836

Wetenschappelijk

TNO Quality of Life,
P.O. Box 2215
K.M. Pal, van der-de Bruin
Leiden 2301 CE
The Netherlands
+31 (0)71 5181836

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Paediatric oncology patients between 1 and 18 years of age with a newly inserted tunnelled central venous catheter (both internal and external devices) will be eligible for the study.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Children who have a documented infection at the time of catheter insertion

2. Children <1 year at diagnosis

3. Children with an existing primary immunological disorder

4. Placement of the central venous catheter in the site of a previously radiographically confirmed venous thrombosis

5. Allergy for ethanol

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-10-2007
Aantal proefpersonen:	600
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	14-04-2008
Soort:	Eerste indiening

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
NTR-new	NL1230
NTR-old	NTR1275
Ander register	AMR project code CC551002 : Financing KIKAnumber 1561
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A