The Aristocaths study

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22330

Source
NTR

Brief title
N/A

Health condition

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

Sponsors and support

Primary sponsor: Academic Medical Center, Amsterdam
Source(s) of monetary or material Support: Dutch Childhood Oncology Group, The Hague

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

Side effects will be registered, focussing on allergic reactions, “flushing” of the face, dizziness, warm feeling and liver (ASAT, ALAT) These reactions will be registered in the first hour after flushing the lock.

Study description

Background summary

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.

Study objective

N/A

Study design

Interim analyses: 1,5 year after start study!

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2007
Enrollment:	600
Type:	Anticipated

Ethics review

Positive opinion

Date:	14-04-2008
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL1230
NTR-old	NTR1275
Other	AMR project code CC551002 : Financing KIKAnumber 1561
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A