

# Ethanol lock solution for the prevention of tunnelled central venous catheter infections in paediatric oncology patients

## A randomized controlled trial

Published: 04-07-2006

Last updated: 14-05-2024

To prove the efficacy and safety of ethanol lock solution in preventing catheter-related infections and subsequently venous thrombosis in children with a malignant disease who will have a tunnelled central venous catheter inserted.

|                              |                                                   |
|------------------------------|---------------------------------------------------|
| <b>Ethical review</b>        | Approved WMO                                      |
| <b>Status</b>                | Pending                                           |
| <b>Health condition type</b> | Hepatobiliary neoplasms malignant and unspecified |
| <b>Study type</b>            | Interventional                                    |

## Summary

### ID

NL-OMON29924

### Source

ToetsingOnline

### Brief title

ethanol lock solution in central lines

### Condition

- Hepatobiliary neoplasms malignant and unspecified

### Synonym

prevention of catheter related infection

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum

**Source(s) of monetary or material Support:** aanvraag ligt bij KWF en KIKa (oncologisch fonds)

## Intervention

**Keyword:** central venous catheter, ethanol-lock, prevention of infection

## 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. Total duration of the study is maximal 6 months.

Secondary endpoint: Occurrence of fever (with or without neutropenia), occurrence of thrombosis (clinical or subclinical), antibiotic use, days of hospital admission, clinical severity of the infection, outcome.

### Secondary outcome

Side-effects will be registered, focussing on allergic reactions, "flushing" of the face, dizziness, warm feeling en liver enzyme raise (ASAT. ALAT) these reactions will be registered in the first hour after flushing the lock.

## Study description

### Background summary

The use of indwelling central venous catheters has become commonplace in the management of children undergoing anticancer treatment. However there are disadvantages such as the risk of infections and the risk of thrombosis. The risk of infection varies between 1.4-2.2 infections per 1000 catheter days. Despite international guidelines on catheter insertion and handling, developed by the Hospital Infection Control Practices committee, infections are still of great importance. Most infections are caused by Gram-positive organisms (70%),

followed by Gram-negative organisms (15%) and fungal organisms (7%). The standard prophylactic measure in inserted catheters in oncology children is flushing with a heparin solution (100U/ml 3 mls) every time the catheter is closed and not used for treatment such as chemotherapy and/or fluid or blood products. No other prophylactic antibiotics are used. This is a routine measure that is widely accepted. Even with these measures infections remain a problem. Therefore newer flush solutions are being evaluated in preventing catheter related infections not used during treatment for fever during neutropenia. An antisepticum not used during neutropenic fever episodes would be preferable. The ethanol lock solution is a promising method of decreasing catheter related infections. Ethanol is a widely used antiseptic with no known acquired resistance. It has been shown that ethanol locks disrupt the biofilm and is lethal to the exposed organisms.

In a cohort study using ethanol lock in addition to systemic antibiotics in the treatment of bloodstream infections in 28 children, 67% of patients had no infectious relapse after ethanol lock within 4 weeks of treatment, compared with 47% treated with systemic antibiotics alone. No side-effects were observed from the ethanol-lock. Few case-reports have been reported using ethanol-lock preventively with success. It was shown that 2 hours of exposure to 70% ethanol is required to kill established biofilms of Gram-positive bacteria, Gram-negative bacteria and candida.

## **Study objective**

To prove the efficacy and safety of ethanol lock solution in preventing catheter-related infections and subsequently venous thrombosis in children with a malignant disease who will have a tunnelled central venous catheter inserted.

## **Study design**

Multi-centered randomized double blind 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 to the treatment.

The lock solution in the experimental group will consist of 3 ml of 70% ethanol. A volume of 3 ml of ethanol will be used to fill each catheter and will be locked in place for 2 hours. This will be repeated once weekly.

Group B (control group): The lock solution will consist of 100U/ml Heparin, the same procedure will be followed where 3 mls is locked into the catheter for 2 hours.

After the two hours the solution will be flushed with normal saline.

## **Study burden and risks**

The extra burden for the patient are the 2 hours the patient has to wait during the placement of the lock, before the catheter can be flushed with normal saline. During the first phase of therapy the patient will be hospitalized frequently for chemotherapy, bloodtransfusions etc. We will plan the lock in a way that the patient has to be here anyway. the patient does not have to come to the hospital only to place the lock. It will be combined with chemotherapy or out-patient visits.

Once a catheter related infection is suspected a sonar of the jugular and subclavian vein will be done to exclude venous catheter thrombosis. At that stage the patient will be hospitalized anyway to treat the infection with iv antibiotics. During this admission the sonar will be done which will have a duration of 15 minutes, it is not painful and not a burden for the patient.

## Contacts

### **Public**

Academisch Medisch Centrum

meibergdreef 9  
1100 DD Amsterdam  
Nederland

### **Scientific**

Academisch Medisch Centrum

meibergdreef 9  
1100 DD Amsterdam  
Nederland

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### **Age**

Adolescents (12-15 years)  
Adolescents (16-17 years)  
Children (2-11 years)

## Inclusion criteria

Paediatric oncology patients age 1-18 years  
who will have a central venous tunneled catheter inserted (internal or external device)

## Exclusion criteria

all patients who have had a previous catheter inserted  
patients with signs and symptoms of infection at time of catheter insertion  
patients <1 year of age  
patients with an allergy for alcohol

## Study design

### Design

|                     |                               |
|---------------------|-------------------------------|
| Study phase:        | 3                             |
| Study type:         | Interventional                |
| Intervention model: | Parallel                      |
| Allocation:         | Randomized controlled trial   |
| Masking:            | Double blinded (masking used) |
| Control:            | Active                        |
| Primary purpose:    | Prevention                    |

### Recruitment

|                           |             |
|---------------------------|-------------|
| NL                        |             |
| Recruitment status:       | Pending     |
| Start date (anticipated): | 01-09-2006  |
| Enrollment:               | 600         |
| Type:                     | Anticipated |

## Ethics review

|                   |                  |
|-------------------|------------------|
| Approved WMO      |                  |
| 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             |
|----------|----------------|
| CCMO     | NL11830.018.06 |