

# An explorative randomized open-label trial of ethanol lock therapy for the additional treatment of catheter-related bloodstream infections (CRI) in pediatric parenteral nutrition patients with intravascular devices

Published: 18-05-2009

Last updated: 05-05-2024

To study the effect of ethanol lock therapy on the cure rate of catheter-related infections (CRIs) and on the incidence of (CRI related) venous thrombosis in pediatric total parenteral nutrition (TPN) patients with tunneled central venous catheters...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Bacterial infectious disorders
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON33319

### Source

ToetsingOnline

### Brief title

Ethanol Lock in Total parenteral nutrition Infections in Children

### Condition

- Bacterial infectious disorders

### Synonym

Catheter related bloodstreaminfection, line-infection

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** ethanol lock children TPN

## Outcome measures

### Primary outcome

Treatment failure is defined as occurrence of 1 of the following endpoints

within

24 weeks after start of ethanol/heparin therapy:

1. Persistent bacteremia >72 hours after start of ethanol/heparin lock OR
2. Recurrence of bacteremia (with the same or other micro-organism) within 24 weeks OR
3. Removal of the CVC OR
4. Occurrence of symptomatic venous thrombosis

### Secondary outcome

Secondary endpoints:

Duration of systemic antibiotic use, mortality, adverse reactions of ethanol-

or

heparin use, number of days of hospital admission.

# Study description

## Background summary

Pediatric patients receiving total parenteral nutrition (TPN). These patients depend on the maintenance of venous access for survival. A high rate of catheter-related infections up to 8.3 per 1000 catheter days has been reported in TPN patients. In order to reduce the incidence of the CRIs and the numbers of CRI related catheter removals, new methods of prophylaxis and treatment have been evaluated in recent years.

These include antibiotic-lock therapy with or without thrombolytic/anticoagulant agents. Recently two retrospective studies reported the positive effect of ethanol lock therapy in pediatric oncology patients on the incidence of (recurrent or persistent) CRI. Up to date there are no prospective data available of ethanol lock therapy for the treatment of CRI in TPN patients. Beside an increased risk for CRIs in long-term TPN patients, central venous thrombosis is a frequent complication described in these patients. A causative relation between catheter-related venous thrombosis and CRI has been described in pediatric oncology patients. A prospective study is needed to evaluate the incidence of central venous thrombosis in relation with the occurrence of a CRI in pediatric TPN patients.

The aim of this randomised study is to evaluate the effect of ethanol lock therapy on the incidence of CRIs and (CRIs related venous thrombosis) in pediatric TPN patients in combination with the standard antimicrobial treatment.

## Study objective

To study the effect of ethanol lock therapy on the cure rate of catheter-related infections (CRIs) and on the incidence of (CRI related) venous thrombosis in pediatric total parenteral nutrition (TPN) patients with tunneled central venous catheters older than 3 months of age.

## Study design

A randomised open-label trial to evaluate the effect of ethanol lock therapy on top of standard care of antimicrobial therapy of catheter-related bloodstream infections and (CRI related) venous thrombosis in pediatric total parenteral nutrition patients with intravascular devices.

## Study burden and risks

In this study, the ethanol is not flushed through the catheter and therefore

the risk of systemic ethanol levels is neglectable. However it may occur that it is not possible to withdraw the ethanol solution and that it has to be flushed. In these cases symptoms may occur and consist of transient light-headedness. After inclusion of 420 adult patients in an ongoing placebo controlled study on the use of ethanol lock 70% at Erasmus MC in Rotterdam no serious drug-related adverse events were observed. The extent of this burden does not weight out the potential benefit of participation, meaning a reduction in incidence of CRIs, hospital admissions and catheter removals and prolonged catheter

## Contacts

### **Public**

Academisch Medisch Centrum

meibergdreef 5  
1105 AZ Amsterdam  
NL

### **Scientific**

Academisch Medisch Centrum

meibergdreef 5  
1105 AZ Amsterdam  
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### **Age**

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

## Inclusion criteria

- \*Pediatric total parenteral nutrition patients older than 3 months of age with a tunnelled central venous catheter (see definition below) with a (clinical) suspicion of a Catheter Related bloodstream Infection (CRI) in which according to the treating physician antimicrobial therapy is indicated. All CRIs will simultaneously be treated with systemic antimicrobial agents according to present local guideline.
- \* patency of all lumina prior to initiation of ethanol locks
- \* written informed consent

## Exclusion criteria

- \* known alcohol allergy
- \* severe clinical sepsis or septic shock, defined as the need for vaso-active drugs or mechanical respiratory support
- \* a positive blood culture with a Staphylococcus aureus or Candida species, (the catheter has to be removed in these cases)
- \* continuous fluid or TPN dependency

## Study design

### Design

Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-02-2009
Enrollment:	10
Type:	Anticipated

## Ethics review

Approved WMO

Application type:

First submission

Review commission:

METC Amsterdam UMC

## 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	NL26618.018.09