An explorative randomised placebo controlled open-label trial of ethanol lock therapy for the treatment of catheter-related bloodstream infections in long term intravascular devices in parenteral nutrition patients (Ethanol lock therapy in TPN patients)

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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 total parenteral nutrition (TPN) patients with tunneled central venous catheters older than...

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

Summary

ID

NL-OMON33739

Source
ToetsingOnline

Brief title
Ethanol Lock in Total parenteral nutrition Infections (ELTI-study)

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: children adults TPN, ethanol lock

Outcome measures

Primary outcome

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

within 24 weeks after start of ethanol/placebo therapy:

1. Persistent bacteremia >72 hours after start of ethanol/placebo lock OR

2. Recurrence of bacteremia (with the same or other micro-organism) within 24

weeks OR

3. Removal of the CVC OR

4. Occurence of symptomatic venous thrombosis

Secondary outcome

Secondary endpoints:

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

or placebo use, number of days of hospital admission.

Study description

Background summary

Catheter-related bloodstream infection (CRI) is an important complication in 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 TPN patients.
The aim of this randomised placebo-controlled study is to evaluate the effect of ethanol lock therapy on the incidence of CRIs and (CRIs related venous thrombosis) in TPN patients older than 3 months of age 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 total parenteral nutrition (TPN) patients with tunneled central venous catheters older than 3 months of age.

Study design

A randomised placebo-controlled 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 total parenteral nutrition patients with intravascular devices.

Intervention

Ethanol lock therapy versus placebo lock therapy.

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 survival time

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

* 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:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2008
Enrollment:	20
Type:	Anticipated

Medical products/devices used

Generic name:	ethanollock
Registration:	Yes - CE intended use

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	NL24035.018.08
Other	nog niet bekend, volgt