Ethanol Lock in Total parenteral nutrition Infections (ELTI study)

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23991

Source
Nationaal Trial Register

Brief title
ELTI

Health condition

children, adults, TPN patients, ethanol lock therapy, catheter-related infection and catheter-related thrombosis

Sponsors and support

Primary sponsor: AMC
Source(s) of monetary or material Support: AMC

Intervention

Outcome measures

Primary outcome

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

- Duration of systemic antibiotic use

- Mortality

- Adverse reactions of ethanol- or placebo use

- Number of days of hospital admission.

Study description

Background summary

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 objective

Ethanol lock therapy in TPN patients reduces the incidence of catheter-related infections and thrombosis.

Study design

Follow-up period of two years

Intervention

Ethanol lock treatment. The instilled lock needs to dwell for a period of 3 -6 hours.

All CRIs will be treated with systemic antimicrobial therapy according to present local bacteriological protocols, being empiric broad spectrum at first and after knowing the susceptibility narrowing the antibiotics.
If this is not possible, the locks will be installed for as long as the patient can be treated without the use of the IVD in between the patient’s TPN or other infusions. In cases of a double lumen IVD the study medication will be instilled in one lumen for 3 - 6 hours while the other lumen can be used for infusion. During the next 3 hours the other lumen will be locked with study medication, while the first lumen is being used for infusions. After the dwell period

is completed, the ethanol-lock will be withdrawn, discarded and followed by a saline flush. This procedure will be repeated for as long as the patient is treated with antibiotics. In case of not being able to discard the study medication it will slowly be infused.

Contacts

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Eligibility criteria

Inclusion criteria

1. TPN patients older than 3 months of age with a tunnelled central venous catheter with a clinical suspicion of a catheter related bloodstream infection

2. Patency of all lumina

3. Written informed consent

Exclusion criteria

1. Known alcohol allergy

2. Severe clinical sepsis or septic shock

3. Positive culture with a Staf. aureus or Candida species

4. 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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2008
Enrollment:	50
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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	NL1307
NTR-old	NTR1356
Other	: AMC ELTI
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A