Ethanol Lock in Total parenteral nutrition Infections (ELTI study)

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

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23991

Bron
Nationaal Trial Register

Verkorte titel
ELTI

Aandoening

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

Ondersteuning

Primaire sponsor: AMC
Overige ondersteuning: AMC

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

Follow-up period of two years

Onderzoeksproduct en/of interventie

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 After the dwell period is completed, the ethanol-lock will be withdrawn, discarded and followed by a saline flush.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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2008
Aantal proefpersonen:	50
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1307
NTR-old	NTR1356
Ander register	: AMC ELTI
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A