

Clinical outcomes of patients with severe intestinal failure on intravenous nutrition at home.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22519

Source

NTR

Health condition

Home parenteral nutrition (HPN)
Olive-oil-based
Severe intestinal failure
Clinical outcomes

Sponsors and support

Primary sponsor: Radboudumc Nijmegen

Source(s) of monetary or material Support: Baxter Inc.

Intervention

Outcome measures

Primary outcome

1. Patient survival.

Secondary outcome

1. Relevant adverse events:
 - Early: hypersensitivity to lipid emulsion components
 - Delayed: bone disease.
2. Serious adverse events (Life threatening events and Hospital admissions).
3. Discontinuation of HPN and reason.
4. Catheter-related bloodstream infections (incidence rate).
5. Catheter-related occlusions (incidence rate).
6. Need for intestinal transplantation (Incidence and cause).

Study description

Background summary

Observational study highlighting the efficacy and safety of long-term use of olive-oil-based home parenteral nutrition in patients with severe intestinal failure in a single center (Radboudumc).

Study objective

To highlight the efficacy and safety of long-term use of olive-oil-based home parenteral nutrition in patients with severe intestinal failure

Study design

1 year study. Half year inclusion of patients from retrospective data in a database. Half year statistics and dissemination of results.

Intervention

Olive-oil-based home parenteral nutrition.

Contacts

Public

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Scientific

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Eligibility criteria

Inclusion criteria

- HPN patients with olive-oil-based HPN for at least 3 months for at least 70% of the time.
- Patients >18 years.

Exclusion criteria

HPN frequency <3 times per week.

Solely intravenous fluids depended patients.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2017
Enrollment:	0
Type:	Anticipated

Ethics review

Positive opinion	
Date:	28-11-2016
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
NTR-new	NL6811
NTR-old	NTR6997
Other	:

Study results