Exploring alternative wound care treatment for percutaneous gastrostomy site infection: A prospective, randomized, open, blinded end-point (PROBE) design.

No registrations found.

Ethical review	Not applicable
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23605

Source
Nationaal Trial Register

Brief title
PEG- Protocol

Health condition

PEG-site infections
Infectie van de PEG-insteekopening

Sponsors and support

Primary sponsor: VU Medical Center, Amsterdam
Source(s) of monetary or material Support: Initiator

Intervention

Outcome measures

Primary outcome

The primary outcome will be the reduction or increase in peristomal sepsis scoring in both groups using the scoring scale of Jain et al.

Secondary outcome

1. The number of patients in which the PEG - site infection was regarded as healed;

2. Percentage decrease in number of bacterial species as measured by the IS-pro;

3. Treatment related adverse events;

4. Recurrence of infection 1 week after healing;

5. Deterioration of the infection-site that will require withdrawal.

Study description

Background summary

To determine the efficacy of silver impregnated dressings compared to a topical antibiotic to treat patients with PEG-site infections.

Study objective

Modern dressings containing silver are more effective than topical antibiotic treatment for healing of PEG-site infections.

Study design

The primary endpoint will be evaluated by a blinded assessor two weeks after treatment.

Intervention

Group 1: Standard treatment with local antibiotic ointment (Fucidin ointment);

Group 2: Treatment with silver-impregnated dressing (Atrauman AG).

Contacts

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Eligibility criteria

Inclusion criteria

1. Signed informed consent;

2. PEG-site infection graded as type 1 & 2 (1= early signs of inflammation,proactive measures, 2= Requiring local antiseptic/antibiotic care);

3. Male and female participants age 18 and older;

4. PEG insertion procedure longer than 1 week prior to randomization;

5. Patient or guardian is able to fully comprehend and perform study procedures.

Exclusion criteria

1. Estimated life expectancy less than one month;

2. Concurrent use of oral antibiotics for other diagnosis;

3. Signs and symptoms of concurrent disease for which the subject is expected to start antibiotic treatment.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2011
Enrollment:	30
Type:	Actual

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	NL2549
NTR-old	NTR2667
Other	: GE10-09
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A