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

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Primary Objective:* To determine the efficacy of silver impregnated dressings compared to a topical antibiotic to treat patients with PEG-site infections.Secondary Objectives:* To investigate the reduction and or change in stomal bacterial profile...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Epidermal and dermal conditions
Study type	Interventional

Summary

ID

NL-OMON36555

Source
ToetsingOnline

Brief title
PEG-protocol

Condition

- Epidermal and dermal conditions

Synonym
stomal infection/ tube infection

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: Het vumc financierd het onderzoek

Intervention

Keyword: Infection, PEG-insertion site, silver, wound care

Outcome measures

Primary outcome

The primary endpoint will be the reduction or increase in peristomal sepsis scoring in both groups as evaluated by the blinded assessor using the validated scoring scale of Jain et al.

Secondary outcome

* The number of patients in which the PEG site infection was regarded as healed after two weeks of treatment. Healing is defined as no sign and symptoms of infection such as erythema, induration , purulent discharge and skin closure as confirmed by the blinded assessor.

* Percentage decrease in number of bacterial species as measured by the IS-pro method.

* Treatment related adverse events

* Recurrence of infection 1 week after healing

* Deterioration of the infection-site that will require withdrawal

Study description

Background summary

Percutaneous endoscopic gastrostomy (PEG) feeding tubes are increasingly used for patients who require medium to longer term nutritional support due to inadequate oral intake. Main indications for insertion are neurological conditions and head and neck malignancies.

There is little doubt about the role of antibiotic prophylaxis to prevent early PEG- wound infections directly before or after placement. However, insertion site infection is the complication most seen in the later stage (longer than 72 hours after insertion) after PEG-placement and reported incidences vary from 5 up to 32%. In a literature search conducted on National Guideline Clearinghouse, Medline and CINAHL no guidelines or evidence as to the management of the (later) infected percutaneous site, nor the role of topical antiseptics or antibiotics to treat these infections were found. Thus, one can conclude that treatment protocols vary in different health-care settings.

Even though infections of PEG-sites have to be addressed promptly to avoid problems with PEG maintenance or a systemic infection, recommendations for the use of topical antibiotics are changing due to increasing antimicrobial resistance and its amplification.

At the Gastroenterology department of the VU medical center of Amsterdam (VUmc) follow-up care after PEG-placement is provided by a team of three specialized nurses and a supervising physician. Infectious complications are assessed and the degree of infection is defined as: 1. early signs of inflammation=proactive measures, 2. requiring local antiseptic/antibiotic care, 3. requiring systemic antibiotics and 4. requiring surgery or PEG-tube removal.
For a infectious complication grade 2, the nurses currently prescribe a topical antibiotic treatment under the supervision of the attending medical staff. Fusidic acid and more recently, erythromycin were the topical antibiotics most prescribed by the nurses and medical staff.

Antiseptic use instead of antibiotics may therefore be a preferable alternative treatment of PEG site infections with regard to bacterial resistance.
The newer type of antiseptic dressings containing nanocrystalline or coated with elemental silver have been designed considering these arguments and are not regarded as harmful.
A systematic review done in 2007 on topical silver dressings concluded that there is little evidence to support the use of silver dressings due to lack of reliable data. The authors argued that the conduct of further appropriate randomized controlled trials are important to guide future decisions on the use of silver-containing dressings in clinical use. Therefore, we propose to compare the current treatment of topical antibiotics with the treatment of the improved silver-impregnated dressings in a randomized, open-label trial.

Study objective

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

Secondary Objectives:

* To investigate the reduction and or change in stomal bacterial profile in the different treatment groups.

* Comparison of pain reduction of the different treatments as measured on a linear visual analogue scale (VAS).

* To investigate recurrence of infection after one week, in both treatments, after healing has occurred.

* To investigate which treatment requires withdrawal of patients from treatment due to no response to treatment or the affected area increasing in size.

* To investigate the ease of use of treatments as experienced by the patient.

Study design

The study is designed as a prospective, randomized open-label trial (PROBE * design).

Intervention

Subjects will be randomized in a 1:1 ratio to 2 weeks of treatment of either topical antibiotic treatment or silver-impregnated dressing treatment.

Study burden and risks

The participants will be burdened with spending a longer periods of time at the hospital (60 minutes in total) Vital signs will be recorden twice, and the patient will be phoned at home twice. There are no benefits or extreme risks for the participating subjects.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Signed informed consent
PEG-site infection graded as type 1 (early signs of inflammation<=proactive measures) & type 2 (requiring local antiseptic/antibiotic care)
Male and female participants age 18 and older
PEG insertion procedure longer than 1 week prior to randomization
Patient or guardian is able to fully comprehend and perform study procedures

Exclusion criteria

Estimated life expectancy less than one month
Concurrent use of oral antibiotics for other diagnosis
Signs and symptoms of concurrent disease for which the subject is expected to start antibiotic treatment
PEG-site infection graded as type 3 (requiring systemic antibiotics) & 4 (requiring surgery or PEG-tube removal)

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-04-2011
Enrollment:	30
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Atrauman AG
Generic name:	Silver-containing impregnated dressing
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Fucidin 20 mg / gram
Generic name:	Sodium fusidate
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	29-03-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO Date:	20-04-2011
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
EudraCT	EUCTR2011-001251-37-NL
CCMO	NL35242.029.11