ISRCTN46568273 https://doi.org/10.1186/ISRCTN46568273

The effect of nasal mupirocin, prior to percutaneous endoscopic gastrostomy (PEG), upon peristomal colonisation and infection

Submission date	Recruitment status	[ ] Prospectively registered
30/09/2004	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/09/2004	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
06/11/2014	Injury, Occupational Diseases, Poisoning	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0547127258

Study information

Scientific Title

Study objectives
Does the treatment, nasal mupirocin, have an effect on peristomal infection rate following percutaneous endoscopic gastrostomy (PEG) placement?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Post-percutaneous endoscopic gastrostomy sepsis

Interventions
Nasal mupirocin versus standard care (no prophylactic antibiotics).

Mupirocin was administered for 5 days before PEG insertion. Nasopharyngeal swabs, PEG site appearance and bacteriology were recorded up to 10 days post-PEG.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Mupirocin

Primary outcome measure
Pilot:
Will access the practicalities of the study design, the consistency of the scoring tool and also give an indication of the bacteriology of nasal colonisation, peristomal colonisation and infection within the proposed research setting.

Main:
The primary outcome measure is that of perstomal infection.

Secondary outcome measures
Secondary outcomes of peristomal colonisation and risk factors for methicillin resistant staphylococcus aureus (MRSA) colonisation will also be measured.

Overall study start date
01/06/2003

Completion date
01/12/2003

Eligibility

Key inclusion criteria
Pilot study of 20 patients recruited, pilot study of 10 controls

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
30

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/06/2003

Date of final enrolment
01/12/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Gastroenterology
Norwich
United Kingdom
NR4 7UY

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
East Norfolk and Waveney Research Consortium (UK) - Norfolk and Norwich University Hospital /Norwich PCT

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration