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Prevention of wound infection in pull-through percutaneous endoscopic gastrostomy

Submission date	Recruitment status	[ ] Prospectively registered
29/09/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
29/09/2006	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
15/03/2017	Surgery	[ ] 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
N0025168201

Study information

Scientific Title
PEG Study: Prevention of wound infection in pull-through percutaneous endoscopic gastrostomy (prospective randomised double-blind trial of novel technique)

Study objectives
The primary aim of the study is to investigate the utility of a polyurethane sheath used during PEG placements in preventing PEG site wound infection.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Prospective randomised double-blind 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
Surgery: Gastrostomy

Interventions
Throat swabs taken at pre-PEG assessment visit; consent; patients carers advised and explained to; demographics taken; examination of the oropharynx prior to PEG insertion; routine antibiotics as per protocol.
Randomisation into 2 groups, group one will undergo standard PEG, group two will undergo PEG insertion modified by use of protective sheath; patient review on the ward at 3/7 and 14 days and wound site assessed. At sign of infection swabs taken; a cohort of patients undergoing direct puncture PEG for pre-operative orophangeal cancer will be monitored; throat swabs taken and PEG wounds assessed/scored in same way as Group 1/2.

Intervention Type
Procedure/Surgery

Phase

Not Specified

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/09/2005

Completion date
01/09/2007

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
60 patients total, 30 in control group.

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/09/2005

Date of final enrolment
01/09/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Gastroenterology
Liverpool
United Kingdom
L9 7AL

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
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Sponsor type
Government

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

Funder(s)

Funder type
Government

Funder Name
Aintree Hospitals NHS Trust (UK)

Funder Name
NHS R&D Support Funding

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