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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

Contact name
Dr Suhail Ahmed

Contact details
Gastroenterology
University Hospital Aintree
Longmoor Lane
Liverpool
United Kingdom
L9 7AL
+44 0151 529 5089
zebi14@hotmail.com

Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Prospective randomised double-blind trial

Study type(s)
Treatment

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(s)
Not provided at time of registration

Key secondary outcome(s)
Not provided at time of registration

Completion date
01/09/2007

Eligibility

Key inclusion criteria

Not provided at time of registration

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

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
United Kingdom

England

Study participating centre
Gastroenterology
Liverpool
United Kingdom
L9 7AL

Sponsor information

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

Funder(s)

Funder type
Government

Funder Name
Aintree Hospitals NHS Trust (UK)

Funder Name
NHS R&D Support Funding

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration