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A prospective study of the incidence of MRSA peristomal infections following gastrostomy insertion and whether infection can be prevented by prophylactic teicoplanin or inserting the tube radiologically.

Submission date 30/09/2005	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol
Registration date 30/09/2005	**Overall study status** Stopped	[ ] Statistical analysis plan [ ] Results
Last Edited 07/04/2011	**Condition category** Signs and Symptoms	[ ] Individual participant data [ ] 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
N0202140085

Study information

Scientific Title

Study objectives
How many patients develop MRSA infection to their gastrostomy site using our present antibiotic prophylaxis and whether infection can be prevented by the use of intravenous teicoplanin or by inserting the gastrostomy tube radiologically rather than endoscopically?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Prospective randomised pilot study

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
Signs and Symptoms: MRSA peristomal infections

Interventions
Use of intravenous teicoplanin or inserting the gastrostomy tube radiologically rather than endoscopically.

Added May 2008: Randomised:
1. RIG + cefotaxime
2. PEG + cefotaxime
3. PEG + teicoplanin

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/06/2004

Completion date
31/12/2006

Reason abandoned (if study stopped)
Interim results no reduction in MRSA infection rate provided either by use of teicoplanin or with the tube being inserted radiologically rather than endoscopically.

Eligibility

Key inclusion criteria
Added May 2008:
1. Subjects over 16 years
2. Referred for PEG/RIG
3. Informed written consent

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Planned 240

Key exclusion criteria
Added May 2008:
1. Oropharyngeal cancer
2. Already taking antibiotics

Date of first enrolment
01/06/2004

Date of final enrolment
31/12/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Cornwall Hospitals NHS Trust
Truro
United Kingdom
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Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
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Sponsor type
Government

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

Funder(s)

Funder type
Government

Funder Name
Royal Cornwall Hospitals NHS Trust (UK)

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