

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/09/2005	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 07/04/2011	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Iain Murray

Contact details
Royal Cornwall Hospitals NHS Trust
Treliske
Truro
United Kingdom
TR1 3LJ
+44
Iain.Murray@rcht.cornwall.nhs.uk

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

TR1 3LJ

Sponsor information

Organisation

Department of Health

Sponsor details

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

+44 (0)20 7307 2622

dhmail@doh.gsi.org.uk

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