

Single dose combination of sulfametoazole /trimethoprim after percutaneous endoscopic gastrostomy

Submission date 13/11/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 04/01/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 04/08/2010	Condition category Surgery	<input type="checkbox"/> Individual participant data

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

Study information

Scientific Title

Single dose combination of sulfamethoxazole/trimethoprim after percutaneous endoscopic gastrostomy versus standard prophylaxis before percutaneous endoscopic gastrostomy: a single centre double blind randomised controlled trial

Study objectives

A single dose combination of a sulfonamide and trimethoprim (Bactrim®), in an oral solution, given in the percutaneous endoscopic gastrostomy (PEG) catheter immediately after the PEG procedure, is as good as the standard prophylaxis with Zinacef® given intravenously minutes before the PEG procedure.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Regional ethical committee in Stockholm approved on the 2nd June 2005 (ref: 2005/505-31)

Study design

Single centre double blind randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Percutaneous endoscopic gastrostomy procedure

Interventions

Single dose of 20 ml oral solution of sulfamethoxazole/trimethoprim (Bactrim®) given in the PEG-catheter immediately after PEG compared to standard treatment (single dose of 1.5 g of cefuroxime [Zinacef®] given intravenously moments before PEG).

Planned follow up once at 7 - 14 days after the PEG procedure in both study arms.

Intervention Type

Drug

Phase

Phase IV

Drug/device/biological/vaccine name(s)

Sulfonamide and trimethoprim (Bactrim®), cefuroxime (Zinacef®)

Primary outcome measure

Parastomal infection at follow up

Secondary outcome measures

Measured at baseline and follow up:

1. Highly sensitive C-reactive protein
2. White blood cell count
3. Body mass index (BMI)
4. Complications

Overall study start date

03/06/2005

Completion date

30/11/2009

Eligibility**Key inclusion criteria**

1. Aged greater than or equal to 15 years, either sex
2. Need for PEG
3. Gives oral consent to the study
4. No contraindication for PEG

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

200 (100 in each arm)

Key exclusion criteria

1. Ongoing antibiotic treatment
2. Allergy to study drug or standard treatment
3. Saying no to participation
4. Too sick to be able to give consent

Date of first enrolment

03/06/2005

Date of final enrolment

30/11/2009

Locations

Countries of recruitment

Sweden

Study participating centre

Unit of Gastrointestinal Research Group (UGIR)

Stockholm

Sweden

17176

Sponsor information

Organisation

Karolinska Institutet (Sweden)

Sponsor details

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Sponsor type

Research organisation

Website

<http://ki.se/ki/jsp/polopoly.jsp?d=130&l=sv>

ROR

<https://ror.org/056d84691>

Funder(s)

Funder type

Research organisation

Funder Name

Swedish Cancer Society (Sweden)

Alternative Name(s)

Swedish Cancer Society

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Sweden

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	02/07/2010		Yes	No