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Single dose combination of sulfametoxazole /trimethoprim after percutaneous endoscopic gastrostomy

Submission date 13/11/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 04/01/2010	**Overall study status** Completed	
Last Edited 04/08/2010	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
2005-100 002

Study information

Scientific Title

Single dose combination of sulfametoxazole/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

Study type(s)
Treatment

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(s)
Parastomal infection at follow up

Key secondary outcome(s))
Measured at baseline and follow up:
1. Highly sensitive C-reactive protein
2. White blood cell count

3. Body mass index (BMI)
4. Complications

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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)

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

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes