

# Single dose combination of sulfametoazole /trimethoprim after percutaneous endoscopic gastrostomy

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

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr John Blomberg

**Contact details**  
Unit of Gastrointestinal Research Group (UGIR)  
Karolinska Institutet  
Norra Stationsgatan 67  
Stockholm  
Sweden  
17176  
+46 (0)8 517 709 83  
john.blomberg@karolinska.se

## Additional identifiers

**Protocol serial number**  
2005-100 002

## 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

### **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?
<a href="#">Results article</a>	results	02/07/2010		Yes	No