Bowel preparation or not in elective colon surgery

Submission date	Recruitment status No longer recruiting	Prospectively registered		
25/07/2005		Protocol		
Registration date 17/11/2005	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	Individual participant data		
19/02/2008	Surgerv			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Erik Nilsson

Contact details

Kirurg Kliniken Norrlands Universitetssjukhus Umeå Sweden 90185 erik.nilsson@surgery.umu.se

Additional identifiers

Protocol serial number N/A

Study information

Scientific Title

Acronym

Boniec

Study objectives

Postoperative complication rate in the bowel preparation group is the same as in the non-bowel preparation group (null hypothesis).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Elective colon surgery

Interventions

The study compares colon surgery with preoperatively given bowel preparation (standard today) with no given bowel preparation preoperatively.

Intervention Type

Procedure/Surgery

Phase

Not Specified

Primary outcome(s)

- 1. Mortality within 30 days postop
- 2. Local infectious complications
- 3. Cardiovascular complications

Key secondary outcome(s))

- 1. Postop bleeding
- 2. Reoperation
- 3. General infectious complications
- 4. Length of postop hospital stay
- 5. Rehospitalisation within 30 days postop

Completion date

11/03/2005

Eligibility

Key inclusion criteria

- 1. Patient aged 18 85 years
- 2. Elective resection for cancer, adenoma or diverticular disease
- 3. Survival over 6 months foreseen
- 4. Written consent after written and spoken information

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

Bowel preparation given preoperatively from other reasons than surgery.

Date of first enrolment

01/01/1999

Date of final enrolment

11/03/2005

Locations

Countries of recruitment

Sweden

Study participating centre Kirurg Kliniken

Umeå Sweden

90185

Sponsor information

Organisation

Umea University/The Health Research Council of South-East of Sweden (FORSS Sydöstra sjukvårdsregionen) (Sweden)

ROR

https://ror.org/05kb8h459

Funder(s)

Funder type

Research council

Funder Name

The Health Research Council of South-East of Sweden (FORSS Sydöstra sjukvårdsregionen) (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	01/06/2007		Yes	No