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Bowel preparation or not in elective colon surgery

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

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
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

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

Overall study start date
01/01/1999

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1500

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)

Sponsor details
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Sponsor type
Research council

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

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	01/06/2007		Yes	No