

# Bowel preparation or not in elective colon surgery

<b>Submission date</b> 25/07/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 17/11/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 19/02/2008	<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**  
Prof Erik Nilsson

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

## 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**

Norrlands Universitetssjukhus  
Umeå  
Sweden  
90185  
[peter.naredi@surgey.umu.se](mailto:peter.naredi@surgey.umu.se)

### **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?
<a href="#">Results article</a>	Results	01/06/2007		Yes	No