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Adhesion prevention with icodextrin

Submission date 04/01/2008	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 22/02/2008	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 22/02/2008	**Condition category** Digestive System	[ ] Individual participant data [ ] Record updated in last year

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

The effect of 4% icodextrin solution vs lactated Ringer's solution on adhesiolysis during Hartmann's reversal: A multi-centre randomised controlled trial

Study objectives
Laparotomy almost always causes peritoneal adhesions, which further causes morbidity and even mortality. A regimen to prevent peritoneal adhesions is urgently needed. Icodextrin has been shown to prevent adhesion formation, and our study investigated further the efficacy of icodextrin in colorectal operation.

Study hypothesis:
4% icodextrin solution decreases adhesion formation and time needed to divide them after hartmann's procedure compared to lactated Ringer's solution.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National approval of the study received on 30 April 2003 from the Ethical Committee of Päijät-Häme Hospital District ETL-code Q36. Further approved by every local ethical committee of participating hospitals.

Study design
Prospective, double-blind, multi-centre, randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Laparotomy/ peritoneal adhesions

Interventions
The study group receives at the end of Hartmann's procedure 1000 ml of 4 % icodextrin instilled into the abdomen. The control group receives same amount of lactated Ringer's solution.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Time needed to separate postoperative adhesions, assessed approximately 3 months after hartmann's reversal procedure
2. Total operative time

Secondary outcome measures
1. Complications and recovery after Hartmann's reversal procedure. Duration of follow-up: 1 month
2. Safety of icodextrin. Duration of follow-up: 1 month

Overall study start date
01/10/2003

Completion date
31/12/2006

Eligibility

Key inclusion criteria
All patients having rectosigmoid colon obstruction, perforation or diverticulitis (with or without perforation) for which a Hartmann's operation was planned

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
40

Key exclusion criteria
1. Refusal to consent
2. Pregnancy
3. Peritoneal carcinoma
4. Postoperative radiotherapy before restorative surgery
5. Reoperation violating study protocol
6. Severe concomitant disease or other reason that would probably interfere with the restorative surgery

Date of first enrolment
01/10/2003

Date of final enrolment
31/12/2006

Locations

Countries of recruitment
Finland

Study participating centre
Department of Surgery
Lahti
Finland
15850

Sponsor information

Organisation
Päijät-Häme Central Hospital (Finland)

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Sponsor type
Not defined

ROR
https://ror.org/02v92t976

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Internally funded by the Päijät-Häme Central Hospital (Finland)

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