

Adhesion prevention with icodextrin

Submission date 04/01/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 22/02/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 22/02/2008	Condition category Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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)

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**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration