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Effect of intravenous fluid restriction on hospital stay and complications after abdominal surgery: a randomised triple-blinded clinical trial

Submission date
28/04/2006

Recruitment status
Stopped

Registration date
28/04/2006

Overall study status
Stopped

Last Edited
13/07/2009

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data
[_] 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

Study objectives
A restrictive fluid regimen is beneficial for postoperative recovery after abdominal surgery, as to hospital stay and postoperative complications.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from the local medical ethics committee

Study design
Randomised triple-blinded clinical trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Abdominal surgery

Interventions
1.5 l intravenous fluid/24 hours versus 2.5 l/24 hours.
Trial was stopped prematurely because of protocol violations due to patient deterioration, with significantly increased postoperative hospital stay (12.3 vs. 8.3 days; p=0.049) and significantly more major complications (12 in 30 (40%) vs. 5 in 32 (16%) patients) in the group with the restricted regime. (detailed in pub 07/07/09)

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome(s)
Length of hospital stay.

Key secondary outcome(s))
1. Postoperative complications
2. Time to restoration of gastric functions and normal diet

Completion date
01/07/2005

Reason abandoned (if study stopped)
Objectives no longer viable

Eligibility

Key inclusion criteria
1. Abdominal surgery
2. Age >18
3. American Society of Anesthesiologists (ASA) I-III
4. Understanding the Dutch language
5. Signed informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Cardiac diseases (New York Hearth Association [NYHA] >III and CCS >III)
2. Contraindications for epidural analgesia
3. Presence of diabetes mellitus
4. Planned for liver or oesophageal surgery
5. Participating in another trial
6. Anticipated postoperative stay in the Intensive Care Unit

Date of first enrolment
01/05/2004

Date of final enrolment
01/07/2005

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Center (AMC)
Amsterdam
Netherlands
1100 DD

Sponsor information

Organisation
Academic Medical Center (AMC), Department of Surgery (Netherlands)

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
University/education

Funder Name
Center for Clinical Practice Guidelines, Academic Medical Center (AMC) (Netherlands)

Funder Name
Dutch Health Care Insurance Board (CVZ, independent government organisation) (Netherlands)

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	07/07/2009		Yes	No