

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/04/2006	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 13/07/2009	Condition category Surgery	<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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 measure

Length of hospital stay.

Secondary outcome measures

1. Postoperative complications
2. Time to restoration of gastric functions and normal diet

Overall study start date

01/05/2004

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

100

Key exclusion criteria

1. Cardiac diseases (New York Heart 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)

Sponsor details

P.O. Box 22660

Amsterdam

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1105 AZ

Sponsor type

University/education

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

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	07/07/2009		Yes	No