

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	☐ Prospectively registered ☐ Protocol
Registration date 28/04/2006	Overall study status Stopped	☐ Statistical analysis plan ☒ Results
Last Edited 13/07/2009	Condition category Surgery	☐ 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
Dr H. Vermeulen

Contact details
Academic Medical Center (AMC)
Department of Surgery, G4-233
P.O. Box 22660
Amsterdam
Netherlands
1100 DD
H.Vermeulen@amc.uva.nl

Additional identifiers

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

Primary study design

Interventional

Study design

Randomised triple-blinded clinical trial

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 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)

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