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

No registrations found.

Ethical review	Positive opinion
Status	Suspended
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23891

Source
NTR

Brief title
N/A

Sponsors and support

Primary sponsor: The study was supported by a grant from the Centre for Clinical Practice Guidelines, Academic Medical Centre at the University of Amsterdam, and the Dutch Health Care Insurance Board.

Intervention

Outcome measures

Primary outcome

Length of hospital stay.

Secondary outcome

1. Postoperative complications;

2. Time to restoration of gastric functions and normal diet.

Study description

Background summary

Background:

Intravenous fluid administration after abdominal surgery is an essential, but variable part of postoperative care. The optimum suppletion volume after abdominal surgery is unknown. In colorectal surgery a restrictive fluid regime was found to reduce complications. We investigated the benefits of a restrictive postoperative intravenous fluid management in patients undergoing elective abdominal surgery.

Methods:

In a triple-blinded trial we randomly allocated patients undergoing elective abdominal surgery to a restrictive postoperative regime of 1,5 litre intravenous fluid/24h vs. 2,5 litre/24h, which was standard hospital practice. Primary outcome measure was length of hospital stay (LOS), secondary measures were postoperative complications and time to restoration of gastric functions and normal diet.

Study objective

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

Study design

N/A

Intervention

1,5 litre intravenous fluid/24h vs. 2,5 litre/24h.

Contacts

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Eligibility criteria

Inclusion criteria

1. Abdominal surgery;

2. Age > 18;

3. ASA I-III;

4. Understanding the Dutch language;

5. Signed informed consent.

Exclusion criteria

1. Cardiac diseases (NYHA > III en CCS > III);

2. Contraindications for epidural analgesia;

3. Presence of diabetes mellitus;

4. Planned for liver or oesophageal surgery;

5. Participating in another trial;

and/or anticipated postoperative stay in the Intensive Care Unit.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	01-05-2004
Enrollment:	100
Type:	Anticipated

Ethics review

Positive opinion

Date:	07-04-2006
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL588
NTR-old	NTR644
Other	: N/A
ISRCTN	ISRCTN16719551

Study results

Summary results
N/A