

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

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

<b>Ethische beoordeling</b>	Positief advies
<b>Status</b>	Werving tijdelijk gestopt
<b>Type aandoening</b>	-
<b>Onderzoekstype</b>	Interventie onderzoek

## **Samenvatting**

### **ID**

NL-OMON23891

### **Bron**

Nationaal Trial Register

### **Verkorte titel**

N/A

### **Ondersteuning**

**Primaire 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.

### **Onderzoeksproduct en/of interventie**

### **Uitkomstmaten**

#### **Primaire uitkomstmaten**

Length of hospital stay.

# Toelichting onderzoek

## Achtergrond van het onderzoek

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.

## Doele van het onderzoek

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

## Onderzoeksopzet

N/A

## Onderzoeksproduct en/of interventie

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

# Contactpersonen

## Publiek

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## **Wetenschappelijk**

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## **Deelname eisen**

### **Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)**

1. Abdominal surgery;
2. Age > 18;
3. ASA I-III;
4. Understanding the Dutch language;
5. Signed informed consent.

### **Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)**

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.

## Onderzoeksopzet

### Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Dubbelblind
Controle:	Actieve controle groep

### Deelname

Nederland	
Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	01-05-2004
Aantal proefpersonen:	100
Type:	Verwachte startdatum

## Ethische beoordeling

Positief advies	
Datum:	07-04-2006
Soort:	Eerste indiening

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

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

## Resultaten

### Samenvatting resultaten

N/A