# Body swelling after surgery: the influence of poor fluid intake, inflammation and the choice of infusion fluid

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
04/05/2014		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
12/06/2014	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
07/02/2018	Surgery			

# Plain English summary of protocol

Background and study aims

Body swelling (a buildup of fluid under the skin) often happens after surgery. The aim of this trial is to investigate the reasons to why it happens. The infusion fluids used in the surgery (e.g. resuscitating fluids), the amount of fluid taken by the patient before the surgery, whether the patient suffers from an inflammatory disease and surgical stress (how the body responds to the surgery) are all possible factors that may influence the amount of swelling that occurs after an operation.

## Who can participate?

Adult patients (aged at least 18 years), scheduled for surgery that will last for longer than 30 minutes.

### What does the study involve?

Urine samples are taken from the patients before, during and after surgery. A blood sample will also be taken the morning after the operation. Patients will be receive either a crystalloid or a colloid infusion fluid during the surgery and be weighted daily until they leave the hospital. Any complications will be recorded.

What are the possible benefits and risks of participating?

The researchers do not believe that there are any benefits or medical risk involved. There may be pain involved when the blood sample is taken.

Where is the study run from? Södertälje Hospital, Sweden

When is the study starting and how long is it expected to run for? June 2012 to September 2015

Who is funding the study? Stockholm County Council (Sweden)

Who is the main contact? Professor Robert Hahn r.hahn@telia.com

# Contact information

# Type(s)

Scientific

### Contact name

Prof Robert Hahn

### Contact details

Research Unit, House 18 Södertälje Hospital Södertälje Sweden 152 86 +46 (0) 855024670 r.hahn@telia.com

# Additional identifiers

## Protocol serial number

2011/657-31/3

# Study information

### Scientific Title

Mechanisms of oedema after general surgery; a randomized clinical trial of the choice of fluid and the influences of preoperative dehydration, inflammation and surgical stress

## Acronym

MPO (Mechanisms of Postoperative Oedema)

# **Study objectives**

That the increase in body weight after surgery can be related to certain preoperative factors.

# Ethics approval required

Old ethics approval format

# Ethics approval(s)

Local Ethics Committee of Stockholm, 29/06/2011, ref. 2011/657-31/3

# Study design

Open randomized trial

# Primary study design

Interventional

# Study type(s)

**Treatment** 

# Health condition(s) or problem(s) studied

General surgery

### **Interventions**

Randomization between using a colloid or a crystalloid fluid for plasma volume support during the surgery. Blood and urine sampling. Recording of postoperative complications according to a prospective survey.

# Intervention Type

Procedure/Surgery

### Phase

Not Applicable

# Primary outcome(s)

Increase in body weight from before up to the morning after surgery

# Key secondary outcome(s))

- 1. Dehydration as evaluated by urine samples before surgery
- 2. Stress and inflammation as detected by serum cortisol and CRP in the morning after the surgery was performed

# Completion date

30/09/2015

# **Eligibility**

# Key inclusion criteria

Adult patients (age >18 years) scheduled for surgery in general anaesthesia lasting for > 30 minutes

# Participant type(s)

**Patient** 

# Healthy volunteers allowed

No

# Age group

Adult

# Lower age limit

18 years

### Sex

All

# Key exclusion criteria

- 1. Endocrinological disease (such as diabetes)
- 2. Kidney disease
- 3. Dementia
- 4. Heart disease that affects physical performance
- 5. Difficulty understanding the Swedish language

### Date of first enrolment

01/06/2012

## Date of final enrolment

30/09/2015

# Locations

# Countries of recruitment

Sweden

# Study participating centre Research Unit, House 18

Södertälje Sweden 152 86

# Sponsor information

# Organisation

Stockholm County Council (Sweden)

### **ROR**

https://ror.org/02zrae794

# Funder(s)

# Funder type

Government

### **Funder Name**

Stockholm County Council (Sweden), grant 20100211

# **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	01/04/2017	Yes	No
Participant information sheet	Participant information sheet	11/11/2025 11/11/2025	No	Yes