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# Renal function and fluid turnover after infusion of saline and Ringer's acetate in elderly males

**Submission date**
30/04/2014

**Recruitment status**
No longer recruiting

**Registration date**
12/06/2014

**Overall study status**
Completed

**Last Edited**
07/02/2018

**Condition category**
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
A non-cancerous enlarging of the prostrate is a common complaint in elderly men. Symptoms include difficulties in urinating, having to urinate more frequently, sudden urges to urinate and not being able to empty the bladder properly. In some cases, surgery is required where the excess prostate tissue is removed in a procedure called transurethral resection of the prostate. During the operation, fluids are used to wash out, or irrigate the bladder, and some of this fluid can enter the blood stream. In rare cases, this can cause the potentially fatal transurethral resection of the prostate syndrome. The aim of this study is to examine whether the fluid used today, saline, is the best choice or whether another fluid, Ringers acetate, should be used.

Who can participate?
Patients scheduled for prostate surgery (transurethral resection of the prostate) due to non-cancerous enlargement of the prostate at Södersjukhuset, Stockholm, and who have to pass urine through a catheter placed in their bladder.

What does the study involve?
Patients receive both fluids on different occasions during the surgery. Their kidney function is measured over 5 periods of 30 minutes each. Blood and urine samples are also taken for calculation of how the fluid is handled by the body.

What are the possible benefits and risks of participating?
There are no specific benefits associated with taking part in the study. There may be some temporary effects on kidney function due to narrowing of the blood vessels during surgery. Breathing problems may occur when the fluids are injected if the patient has undetected heart problems. There may also be some pain associated with placement of the venous cannulae (tube for administrating intravenous fluids)

Where is the study run from?
Department of Urology, Södersjukhuset, Sweden.

When is the study starting and how long is it expected to run for?
February 2013 to February 2015

Who is funding the study?
Södersjukhuset and Södertälje hospital, Sweden

Who is the main contact?
Professor Robert Hahn
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# Contact information

### Type(s)
Scientific

### Contact name
Prof Robert Hahn

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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
2008/804-31/2

# Study information

### Scientific Title
Glomerular filtration rate and fluid volume kinetics of isotonic saline versus Ringer's acetate in males scheduled for transurethral resection of the prostate

### Acronym
SIE (Saline In the Elderly)

### Study objectives
Transurethral resection of the prostate is a surgical method of alleviating bladder outlet obstruction caused by prostatic hypertrophy, which is a common disease in elderly men. The operation is usually performed using isotonic saline as the irrigating solution. However, the irrigating medium might be absorbed by the patient and various amounts of the irrigating fluid

thus be transported the the circulation. Saline is probably not the optimal solution to use, as balanced electrolyte solutions like Ringer's acetate show greater similarity to the composition of the extracellular fluid than saline. Importantly, glomerular filtration rate has been shown to be reduced in young volunteers.

We hypothesize that Ringer's acetate has a smaller effect on the glomerular filtration rate than isotonic saline when infused intravenously in patients scheduled for transurethral resection of the prostate. We also want to investigate, by using fluid kinetics, whether the body handles isotopic saline and Ringer's acetate differently in these primarily old males.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Regional ethics committee of Stockholm on 11/06/2008, ref. 2008/804-31/2

### Study design
Open randomized cross-over single-centre

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Treatment

### Participant information sheet
Patient information can be found at: http://roberthahn.se/Saline.pdf

### Health condition(s) or problem(s) studied
Transurethral resection of the prostate

### Interventions
Infusion of two electrolyte isolations (saline and Ringer's acetate) on two different occasions. Continuous infusion of iohexol (an X-ray contrast medium that can be used to measure glomerular filtration rate), blood sampling and urine sampling on 12 occasions during each experiment.

### Intervention Type
Procedure/Surgery

### Phase
Not Applicable

### Primary outcome measure

Glomerular filtration rate, measured using continuous infusion of iohexol during five periods of 30 minutes each, starting 30 min after the study begins and 30 min after the fluid infusion is started

### Secondary outcome measures
Fluid volume kinetics based on blood and urine sampled during the last 3 hours of each experiment

### Overall study start date
14/02/2013

### Completion date
28/02/2015

## Eligibility

### Key inclusion criteria
Patients scheduled for transurethral resection of the prostate due to benign enlargement of the prostate at Södersjukhuset, Stockholm, who have an indwelling bladder catheter

### Participant type(s)
Patient

### Age group
Senior

### Sex
Male

### Target number of participants
12

### Key exclusion criteria
Patients with severe renal disease (serum creatinine > 120) or heart disease (ASA group III)

### Date of first enrolment
14/02/2013

### Date of final enrolment
28/02/2015

## Locations

### Countries of recruitment
Sweden

### Study participating centre

**Research Unit**
Södertälje
Sweden
152 86

# Sponsor information

**Organisation**
Södersjukhuset (Sweden)

**Sponsor details**
Department of Urology
Stockholm
Sweden
118 83

**Sponsor type**
Hospital/treatment centre

**Website**
http://www.sodersjukhuset.se/

# Funder(s)

**Funder type**
Hospital/treatment centre

**Funder Name**
Södersjukhuset (Sweden)

# 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 | 01/02/2016 | | Yes | No |