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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
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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