ISRCTN34433361 https://doi.org/10.1186/ISRCTN34433361

To test whether the anthroposophical drug Stibium D6 has beneficial effect on blood clotting in patients undergoing transurethral resection of the prostate

Submission date
02/07/2012

Recruitment status
No longer recruiting

Registration date
30/07/2012

Overall study status
Completed

Last Edited
30/07/2012

Condition category
Haematological Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
We are carrying out a study of 136 patients who are scheduled for transurethral resection of the prostate (surgical procedure that involves cutting away a section of the prostate gland). During this operation, there is a high risk for bleeding. Therefore, we will test the drug Stibium D6 in order to evaluate its benefit of reduction of bleeding complications. We also test the blood clotting time in 20min intervals during the operation.

Who can participate?
We aim to recruit 136 men, age > 18 years who are scheduled for a transurethral resection of the prostate.

What does the study involve?
Patients will be randomly allocated to receive Stibium D6 intravenous (i.v.) or placebo (dummy). During the operation (under anaesthesia), four blood samples are taken at the beginning of the operation as well as after every 20min. Another blood sample will be taken 1 and 2 days after surgery, respectively. A control examination in our outpatient clinics will be 2 weeks after the operation.

What are the possible benefits and risks of participating?
There could be a direct benefit to those taking part and getting the real drug regarding bleeding complications. If the drug has a beneficial effect on blood clotting, there should be benefits to future patients undergoing transurethral resection of the prostate. Eventually, the drug could be used in surgical interventions other than transurethral resection of the prostate..
The main risk of the intervention is the extra samples of blood that has to be taken. However, the amount of blood is very small. There is no risk for iron deficiency and the related anaemia because of the blood samples. So far, there is no known risk of administering Stibium D6.

Where is the study run from?
The study has been set up by the Urology Department of the University of Bern.

When is study starting and how long is it expected to run for?
It is anticipated that recruitment will start July 2012. Participants will be enrolled on the study for a period of two years.

Who is funding the study?
University Clinic of Urology (Urologische Universitaetsklinik), Switzerland

Who is the main contact?
Dr Beat Roth
urology.berne@insel.ch

Contact information

Type(s)
Scientific

Contact name
Dr Beat Roth

Contact details
Urologische Universitaetsklinik
Inselspital
Bern
Switzerland
3010

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
DR2046

Study information

Scientific Title
Double blinded, randomized, placebo-controlled trial to evaluate the efficacy of Stibium D6 on clotting in patients undergoing transurethral resection of the prostate (TURP)

Study objectives
The anthroposophical drug Stibium D6 has beneficial effect on blood clotting in patients undergoing TURP

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee of the Canton Bern, Switzerland, 03/2012, ref: 235/10

Study design
Randomized double-blinded placebo-controlled single center trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Clotting disorder / intraoperative bleeding / transurethral resection of the prostate

Interventions
Transurethral resection of the prostate in all patients.

50% of patients will receive placebo during this intervention, 50% will receive Stibium D6 intravenous (i.v.).

Stibium D6 -dose: 10ml of 0.000001%, Stibium D6 in 250ml 0.9% NaCl

Total duration of intervention: approximately 1 hour

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Stibium D6

Primary outcome measure
1. Complications (especially bleeding complications), bleeding complications are measured during the first 14 postoperative days (final evaluation during the final outpatient visit 14 days

following surgery)
2. Blood clotting time measured at the beginning of the operation, after 20, 40 and 60 minutes of operation as well as on the 1st and 2nd postoperative day.

Secondary outcome measures
1. Intraoperaperative bleeding score measured during operation
2. Readmissions to hospital evaluated within the first 30 postoperative days
3. Duration of TURP
4. Blood glucose levels measured during operation
5. Duration of catheter in place measured within the first 2 postoperative days (during hospitalisation).
6. Time of postoperative bladder flushing required measured within the first 2 postoperative days (during hospitalisation)

Overall study start date
01/07/2012

Completion date
30/06/2014

Eligibility

Key inclusion criteria
1. Male
2. >18 years
3. Written informed consent
4. Scheduled for transurethral resection of the prostate

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
136

Key exclusion criteria
1. Peripheral artery occlusive disease
2. Coronary hart disease
3. Anticoagulation therapy (e.g. cumarines)
4. History of stroke
5. Clotting disorder
6. Allergy / intolerance to Stibium D6

Date of first enrolment
01/07/2012

Date of final enrolment
30/06/2014

Locations

Countries of recruitment
Switzerland

Study participating centre
Urologische Universitaetsklinik
Bern
Switzerland
3010

Sponsor information

Organisation
University Clinic of Urology (Urologische Universitaetsklinik) (Switzerland)

Sponsor details
c/o Dr Beat Roth
Inselspital
Bern
Switzerland
3010

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01q9sj412

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Clinic of Urology (Urologische Universitaetsklinik) (Switzerland)

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