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Selection of candidates for surgery by means of three separate blind administered high scrotal injections in men with chronic scrotal pain and objective evaluation of these patients

Submission date
28/08/2013

Recruitment status
No longer recruiting

Registration date
23/10/2013

Overall study status
Completed

Last Edited
04/05/2020

Condition category
Signs and Symptoms

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

Plain English summary of protocol

Background and study aims
Chronic scrotal pain can be treated by surgery as a last resort. The surgical procedure is called microsurgical denervation of the spermatic cord. We think that patients who are carefully selected for surgery have a better outcome than patients who receive surgery without any kind of screening. Screening (by means of a preoperative temporary injection with an anesthetic) is already considered 'best practice' so we can only compare our results with those in previous studies. The aim is to determine the pain reduction rate after injections and prior to surgery and to confirm that patients that are screened that way have better results.

Who can participate?
All men who fit the definition of chronic scrotal pain: intermittent or constant pain of varying degree in one or both testicles for a duration of at least 3 months which leads to significant reduction of daily activities with no underlying cause.

What does the study involve?
All men with chronic scrotal pain are invited to the pain clinic where they receive 3 injections (called inguinal temporary nerve blockades): a short-lasting anaesthetic, a long-lasting anaesthetic an a dummy injection (called a placebo) in a random order.
Patients who achieve more than 50% reduction in pain can have surgery.
If patients realise that they received the dummy injection and the pain reduction is at least 50%, a microsurgical denervation is offered to permanently cut the nerve fibers.
Patients who are not eligible for surgery are referred to the pain clinic to undergo spinal cord blockades or alternative treatment with drugs/psychotherapy.
The screening process is a test to determine if the patients are eligible for surgery, because all 3 injections are administered to one patient. The patient itself is his own 'control. We are not trying to assess whether the order of the injections has an impact on the % of pain reduction.

Where is the study run from?
The University Medical Centre Utrecht, Netherlands.

When is the study starting and how long is it expected to run for?
It started in 1999 and is ongoing.

What are the possible benefits and risks of participating?
There are very few to no risks for participants. The injections are performed with a short-acting anaesthetic (lidocain or bupivacain). In most hospitals, an injection with a local anaesthetic is a standard procedure before performing surgery. The injections take place on three different days and takes about a 1/2 hour.

Who is funding the project?
Overall the Department of Urology, University Medical Center Utrecht (Universitair Medisch Centrum Utrecht) (Netherlands). Injections prior to surgery are part of standard care and there is no specific additional funding.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Prospective double-blind preoperative pain clinic screening before microsurgical denervation of the spermatic cord in patients with chronic orchialgia

Study objectives
What is the efficacy in terms of pain reduction after surgery (microsurgical denervation of the spermatic cord) after carefully screening patients by means of three blockades in a randomized order?

Ethics approval required
Old ethics approval format

Ethics approval(s)
None, the injections and surgery are standard of care.

Study design
Prospective double-blind observational study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Screening

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
Chronic orchialgia

Interventions
All men included in the study suffer from orchialgia on the right or left or both sides.
Prior to possible surgery (inguinal approach for microsurgical denervation of the spermatic cord) all men undergo 3 injections in the high scrotal region to give a depot around the spermatic cord for temporary nerve blockade.
All patients will have 3 temporary nerve blockades on one side in a randomized order: bupivacain, lidocain and placebo in 3 separate sessions (mostly 1 week in between).
If a pain reduction above 50% happens during a reasonable period (bupivacain 4-12 hours, lidocain 2-6 hours, placebo no effect) they are candidates for surgery.
Only one side at a time is evaluated and operated on.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Pain reduction after surgery
Outpatient clinic evaluation at 6 weeks and three months postoperatively and thereafter yearly by telephone interviewing (in case of complaints, patients are always seen immediately)

Secondary outcome measures
1. Patient satisfaction
2. Complications
3. Evaluation of blockades in randomized order

Overall study start date
01/01/1999

Completion date
01/01/2014

Eligibility

Key inclusion criteria
All patients with chronic orchialgia by definition: intermittent or constant pain of varying degree in one or both testicles for a duration of at least 3 months with leads to significant reduction of daily activities with no underlying cause

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
300

Total final enrolment
180

Key exclusion criteria
1. Underlying treatable causes
2. Psychiatric disorders that could be the cause of the pain

Date of first enrolment
01/01/1999

Date of final enrolment
01/01/2013

Locations

Countries of recruitment
Netherlands

Study participating centre
Heidelberglaan 100
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Sponsor information

Organisation
University Medical Center Utrecht (Universitair Medisch Centrum Utrecht) (Netherlands)

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Sponsor type
University/education

ROR
https://ror.org/0575yy874

Funder(s)

Funder type
University/education

Funder Name
Department of Urology, University Medical Center Utrecht (Universitair Medisch Centrum Utrecht) (Netherlands)

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	01/09/2014	04/05/2020	Yes	No