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Treatment of Peyronie's disease with hyperthermia, vitamin D and testosterone: a pilot randomised controlled trial

Submission date	Recruitment status	[X] Prospectively registered
29/09/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/10/2007	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
25/02/2010	Urological and Genital Diseases	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

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

Study objectives
To evaluate the effectiveness and safety of the combination of hyperthermia, vitamin D and testosterone in the treatment of Peyronie's disease compared with hyperthermia alone.

As of 25/02/2010 this record was updated to reflect a change to the study design of this trial. This is now a pilot randomised controlled trial instead of a randomised controlled trial. At this time, the anticipated trial dates were also updated; the previous anticipated trial dates were as follows:
Initial anticipated start date: 26/09/2007
Initial anticipated end date: 26/03/2010
Also, the target number of participants has been amended from 60 participants to 20 participants.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the ethics committee of Hospital de Clinicas da Universidade Federal do Parana (Brazil) on the 19th September 2007 (ref: CAAE: 01730208000-07; CEP/HC: 1489.154/2007-07).

Study design
Pilot randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Peyronie's disease

Interventions
Please note that as of 06/02/2008 the anticipated end date of this trial was extended to 26/03/2010. The previous anticipated end date was 26/09/2008.

Current interventions as of 25/02/2010:
The interventions will take place with a duration of 16 weeks. At baseline, all patients will be analysed clinically and with lab exams:
1. Total and free testosterone
2. Prostate specific antigen (PSA)
3. Haemogram
4. Prolactin
5. Luteinising hormone (LH)
6. Digital rectal examination
7. Ultrasonography of penis and photos of penis during erection

Patients will be randomised to:
1. Control group:10 patients will be treated with hyperthermia alone during 30 minutes/day with infrared laser applied directly over the plaque and curvature for 16 weeks.
2. Experimental group: 10 patients will be treated with hyperthermia (as above) plus Vitamin D 30.000 UI/day/oral and an injection of testosterone depot (Durateston®) every 10 days initially (patients with baseline levels of free testosterone under upper normal levels)

All patients will have to return every month and levels of testosterone and vitamin D will be analysed (patients of the experimental group) to reach the goal of upper normal levels of free testosterone and maximum non-toxic normal level of vitamin D. At the end of 16 weeks, patients of the experimental group will have their levels of PSA and haemogram analysed as well as digital rectal examination.

Both groups at the end of 16 weeks will have ultrasonography of penis and will take photos of their penis during erection.

Initial information at time of registration:
The interventions will take place over a duration of one year. At baseline, all patients will be analysed clinically and with lab exams:
1. Total and free testosterone
2. Prostate Specific Antigen (PSA)
3. Haemogram
4. Prolactin
5. Luteinising Hormone (LH)
6. Digital rectal examination
7. Ultrasonography of penis and photos of penis during erection

Patients will be randomised to:
1. Control group: 30 patients will be treated with hyperthermia alone (30 minutes/day with infrared lamp of 150 W at a distance of approximately 20 cm of the plaque(s) and curvature)
2. Experimental group: 30 patients will be treated with hyperthermia (as above) plus Vitamin D (4000 IU/day/oral) and one injection of Testosterone depot (Durateston®) every 2 weeks initially (patients with baseline levels of free testosterone under median normal level)

All patients will have to return every month and levels of testosterone and vitamin D will be analysed to reach the goal of median normal level of free testosterone and maximum normal level of vitamin D. Every 3 months, levels of PSA and Haemogram will be analysed and at 6 months and 1 year digital rectal examination and also ultrasonography and photos of penis on erection will be analysed.

Intervention Type

Supplement

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Vitamin D and testosterone (Durateston®)

Primary outcome measure
1. Decreased size of plaques, measured every month throughout the duration of the trial
2. Decreased curvature of penis, measured every month throughout the duration of the trial

Secondary outcome measures
1. Improvement of sexual function, measured every month throughout the duration of the trial
2. Improvement of self-esteem, measured every month throughout the duration of the trial

Overall study start date
01/04/2010

Completion date
01/04/2011

Eligibility

Key inclusion criteria
Patients with Peyronie's disease.

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
20 patients

Key exclusion criteria
1. Prostate cancer
2. Hyperprolactinaemia
3. Congestive heart failure
4. Severe dyslipidemia
5. Severe hypertension

Date of first enrolment
01/04/2010

Date of final enrolment

01/04/2011

Locations

Countries of recruitment
Brazil

Study participating centre
Rua Oyapock , 67 Apart 101
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Sponsor information

Organisation
Hospital de Clinicas da Universidade Federal do Paraná (UFPR) (Brazil)

Sponsor details
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Rua General Carneiro, 181
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Brazil
80060-900

Sponsor type
Hospital/treatment centre

Website
http://www.hc.ufpr.br/

ROR
https://ror.org/03ej9xm26

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded trial (Brazil)

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