

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

Submission date 29/09/2007	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 30/10/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 25/02/2010	Condition category Urological and Genital Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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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 IU/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

Curitiba (State of Parana)

Brazil

80050-450

Sponsor information

Organisation

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

Sponsor details

c/o Miss Simone

Rua General Carneiro, 181

Curitiba (State of Parana)

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