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# 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

**Registration date**
30/10/2007

**Overall study status**
Completed

**Last Edited**
25/02/2010

**Condition category**
Urological and Genital Diseases

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

## 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).

## Primary study design
Interventional

## Study design
Pilot randomised controlled trial

## Study type(s)
Treatment

## 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(s)
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

## Key secondary outcome(s)
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

## Completion date

01/04/2011

# Eligibility

### Key inclusion criteria
Patients with Peyronie's disease.

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
Male

### 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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80050-450

# Sponsor information

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

**ROR**
https://ror.org/03ej9xm26

# Funder(s)

**Funder type**
Other

**Funder Name**
Investigator initiated and funded trial (Brazil)

# Results and Publications

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration