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# Shock wave therapy (SWT) vs observation only (sham therapy) for Peyronie's disease

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 30/09/2005 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 30/09/2005 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 02/10/2014 | Urological and Genital Diseases | |

**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**
N0547145275

# Study information

## Scientific Title
Prospective randomised controlled double-blind trial of shock wave therapy (SWT) vs observation only (sham therapy) for Peyronie's disease

## Study objectives
To confirm the question of efficacy of shock wave therapy (SWT) in patients randomised to the treatment arm and assess whether an active treatment such a SWT leads to statistically significant improvement in these patients compared to that achieved by natural resolution.

On 19/08/2008 the following changes were made to the trial record:
1. The public trial title was changed from "Prospective Randomised Trial of Shock Wave Therapy vs Conservative Management of Peyronie's Disease" to "Shock wave therapy (SWT) vs observation only (sham therapy) for Peyronie's disease".
2. The scientific title was added.
3. The anticipated start date was changed from 01/04/2004 to 01/01/2005.
4. The anticipated end date was changed from 31/03/2006 to 12/12/2006.
5. The sources of funding field was updated.

Previous sources of funding:
1. East Norfolk and Waveney Research Consortium - Norfolk and Norwich University Hospital /Norwich PCT
2. NHS R&D Support Funding

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Norfolk Research and Ethics Committee, 19/08/2004, ref: 04/Q0101/46

## Study design
Double-blind randomised controlled trial

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Not specified

## Study type(s)
Treatment

## Participant information sheet

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

### Interventions
Six sessions of SWT over a period of 6 weeks at a rate of one session per week vs observation only (sham therapy).

### Intervention Type
Other

### Phase
Not Applicable

### Primary outcome measure
Current primary outcome measures as of 19/08/2008:
1. Mean change in angle of deformity for each arm of the study
2. Difference in mean change in angle between treatment and non-treatment arm
3. Difference in the mean International Index of Erectile Function (IIEF) scores pre and post treatment in each group

All primary and secondary outcomes were measured at 6 months post-therapy.

Previous primary outcome measure:
Reduction in the angle of penile deformity

### Secondary outcome measures
Current secondary outcome measures as of 19/08/2008:
The difference in pain scores measured by a visual analogue scale (VAS) and Global Assessment Questionnaire (GAQ) scores between two groups

All primary and secondary outcomes were measured at 6 months post-therapy.

Previous secondary outcome measures:
Improvement in pain scores (VAS) and erectile function scores (IIEF) and partner satisfaction

### Overall study start date
01/01/2005

### Completion date
12/12/2006

## Eligibility

### Key inclusion criteria
Current inclusion criteria as of 19/08/2008:
1. Penile deformity secondary to Peyronie's disease affecting ability to perform sexual intercourse and/or quality of life due to penile angulation
2. Age >18

Previous inclusion criteria:
1. 40-60 in each arm
2. Patients with suspected Peyronie's disease

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Male

### Target number of participants
40-60 in each arm

### Key exclusion criteria
Current exclusion criteria as of 19/08/2008:
1. Congenital curvature of the penis
2. Previous treatment for Peyronie's disease
3. Patients on warfarin

Previous exclusion criteria:
1. Patients on warfarin
2. Patients with total erectile dysfunction (ED)

### Date of first enrolment
01/01/2005

### Date of final enrolment
12/12/2006

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
**Department of Urology**
Norwich
United Kingdom
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## Sponsor information

### Organisation
Norfolk and Norwich University Hospitals NHS Foundation Trust (UK)

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### Sponsor type
Hospital/treatment centre

### Website
http://www.nnuh.nhs.uk

### ROR
https://ror.org/01wspv808

## Funder(s)

### Funder type
Government

### Funder Name
Focus Medical Services (UK)

### Funder Name
Norfolk and Norwich University Hospitals NHS Foundation Trust (UK)

## 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 | 01/11/2010 | | Yes | No |