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

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

### Plain English summary of protocol

Not provided at time of registration

### **Contact information**

**Type(s)** Scientific

**Contact name** Mr Sudhanshu Chitale

### Contact details

Department of Urology Norfolk and Norwich University Hospital NHS Trust Colney Lane Norwich United Kingdom NR4 7UY +44 (0) 1603 286776 sudhanshu.chitale@nnuh.nhs.uk

# 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 NR4 7UY

### Sponsor information

#### Organisation

Norfolk and Norwich University Hospitals NHS Foundation Trust (UK)

### Sponsor details

Colney Lane Norwich England United Kingdom NR4 7UY +44 (0) 1603 286776 sudhanshu.chitale@nnuh.nhs.uk

**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?
<u>Results article</u>	results	01/11/2010		Yes	No