

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

Submission date 30/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 30/09/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 02/10/2014	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

Protocol serial number
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

Primary study design

Interventional

Study design

Double-blind randomised controlled trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Male

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

United Kingdom

England

Study participating centre

Department of Urology

Norwich

United Kingdom

NR4 7UY

Sponsor information

Organisation

Norfolk and Norwich University Hospitals NHS Foundation Trust (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

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