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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

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

Study design
Double-blind randomised controlled trial

Primary study design
Interventional

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