

Home orthostatic training in vasovagal syncope (The HOT VVS-1 study): A placebo controlled trial

Submission date 29/09/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 29/09/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 25/01/2010	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

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
N0503172648

Study information

Scientific Title

Acronym

The HOT VVS-1 study

Study objectives

Added 19/11/09:

To detect possible autonomic changes due to home orthostatic training (HOT) and to assess the feasibility of a larger, placebo-controlled study of HOT in vasovagal syncope (VVS).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised single-blind placebo controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Vasovagal syncope

Interventions

Home orthostatic training versus sham training in vasovagal syncope

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Number of syncopal episodes in each patient group, which will assess the efficacy of orthostatic training.

Secondary outcome measures

1. Time to tilt-positivity
2. Time to first spontaneous syncope or pre-syncope (where this was the symptom at presentation)
3. Number of patients experiencing syncope or pre-syncope during follow-up
4. Frequency of symptoms

In addition, autonomic function tests will assess the mechanism by which orthostatic training works and improve the understanding of the mechanism behind vasovagal syncope.

The impact of orthostatic training will be assessed using quality of life measures.

Overall study start date

01/06/2005

Completion date

31/05/2006

Eligibility

Key inclusion criteria

Consecutive patients aged 18+ diagnosed with head-up tilt positive vasovagal syncope.

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

40 (20 in each arm of the study)

Key exclusion criteria

1. Inability to give informed consent
2. Patients on drugs which can affect the autonomic nervous system which cannot be discontinued safely
3. Inability to stand for up to 40 minutes due to muscular or neurological disorders, cardiac transplantation or pregnancy

Date of first enrolment

01/06/2005

Date of final enrolment

31/05/2006

Locations

Countries of recruitment

England

United Kingdom

Study participating centre**Department of Medicine**

Newcastle Upon Tyne

United Kingdom

NE1 4LP

Sponsor information

Organisation

Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Sponsor details

The Department of Health, Richmond House, 79 Whitehall

London

United Kingdom

SW1A 2NL

+44 (0)20 7307 2622

dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type

Government

Funder Name

Newcastle upon Tyne Hospitals NHS Trust (UK)

Alternative Name(s)

Newcastle upon Tyne Hospitals NHS Trust

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

United Kingdom

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	01/02/2010		Yes	No