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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 29/09/2006	**Overall study status** Completed	
Last Edited 25/01/2010	**Condition category** Circulatory System	

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