ISRCTN17688061 https://doi.org/10.1186/ISRCTN17688061

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

Submission date	Recruitment status	[_] Prospectively registered
29/09/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/09/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
25/01/2010	Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr SW Parry

Contact details
Department of Medicine
Royal Victoria Infirmary
Newcastle Upon Tyne
United Kingdom
NE1 4LP

Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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

Key secondary outcome(s))
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.

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
United Kingdom

England

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

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

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