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Treatment strategy in patients with recurrent vasovagal syncope

Submission date 20/12/2005	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 20/12/2005	**Overall study status** Completed	
Last Edited 18/11/2008	**Condition category** Signs and Symptoms	

Plain English Summary
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
NHS 2003B156; NTR143

Study information

Scientific Title

Acronym
STAND (Syncope Treatment Association Netherlands Danmark)

Study hypothesis
1. In patients with recurrent vasovagal syncope, current conventional therapy will fail in 40%, after 1 year follow-up
2. In patients with recurrent vasovagal syncope, treated with conventional therapy and training in physical counter pressure manoeuvres, failure rate will be reduced to 20% (50% reduction) and quality of life will improve significantly
3. In the subgroup of patients with recurrent vasovagal syncope, refractory to training in physical counter pressure manoeuvres, Midodrine therapy will lead to a recurrence rate of less than 20% and will improve quality of life significantly

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from the local medical ethics committee

Study design
Multicentre, randomised, single-blind, active controlled, crossover trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Condition
Vasovagal syncope

Interventions
1. Physical counterpressure manoeuvres for all patients
2. Midodrine - crossover therapy
Double-blind randomisation is used to decide whether patients first receive midodrine or placebo.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Syncope recurrences during an entire treatment protocol including both physical counterpressure manoeuvres and the use of medication (midodrine)
2. The number of patients with recurrences during treatment with midodrine after recurrent failure of using the manoeuvres

Secondary outcome measures
1. Time to first recurrence syncope and presyncope
2. Presyncope burden
3. Quality of life

Overall study start date
02/01/2005

Overall study end date
02/01/2008

Eligibility

Participant inclusion criteria
1. Clinical diagnosis of classical neurally-mediated reflex syncope, based on the medical history or non-classical diagnosis of neurally-mediated reflex syncope and a positive tilt-table test
2. Three syncope episodes in the last year
3. Recognisable prodromal symptoms
4. Aged 18 - 70 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
300

Participant exclusion criteria
1. Suspected or certain heart disease and high likelihood of cardiac syncope
2. Orthostatic hypotension

3. Episodes of loss of consciousness different from syncope (e.g. epilepsy, psychiatric, metabolic, drop-attack, transient ischaemic attack [TIA], intoxication, cataplexy)
4. Steal syndrome
5. Psychologically or physically (due to any other illness) or cognitively unfit for participation in the study according to the opinion of the investigator
6. Patient compliance doubtful
7. Patient geographically or otherwise inaccessible for follow-up
8. Patient unwilling or unable to give informed consent
9. Pregnancy
10. Life expectancy less than 1 year

Recruitment start date
02/01/2005

Recruitment end date
02/01/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Centre
Amsterdam
Netherlands
1105 AZ

Sponsor information

Organisation
Academic Medical Centre (AMC) (Netherlands)

Sponsor details
Meibergdreef 9
Amsterdam
Netherlands
1105 AZ

Sponsor type
University/education

Website
http://www.amc.uva.nl/

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Research organisation

Funder Name
Netherlands Heart Foundation (Nederlandse Hartstichting) (The Netherlands)

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