

Treatment strategy in patients with recurrent vasovagal syncope

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

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
NHS 2003B156; NTR143

Study information

Scientific Title

Acronym

STAND (Syncope Treatment Association Netherlands Danmark)

Study objectives

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

Health condition(s) or problem(s) studied

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

Completion date

02/01/2008

Eligibility**Key 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

Key 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

Date of first enrolment

02/01/2005

Date of final enrolment

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