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Treatment strategy in patients with recurrent vasovagal syncope

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

Protocol serial number
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

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s))

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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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)

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Research organisation

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

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration