Treatment strategy in patients with recurrent vasovagal syncope.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28970

Source
NTR

Brief title
STAND (Syncope Treatment Association Netherlands Danmark)

Health condition

Vasovagal syncope

Sponsors and support

Primary sponsor: Academic Medical Center
Source(s) of monetary or material Support: Netherlands Heart Foundation

Intervention

Outcome measures

Primary outcome

Total burden of syncope recurrence.

Secondary outcome

1. Time to first recurrence syncope and presyncope;

2. Presyncope burden;

3. Quality of life.

Study description

Background summary

Patients with recurrent vasovagal syncope will be randomised between conventinal therapy alone of additional training in counterpressure manoeuvres.

In case of recurrence a trial with midodrine (double nlind cross over) will be added to the therapy.

Study objective

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 counterpressure 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 counterpressure manoeuvres, Midodrine therapy will lead to a recurrence rate of less than 20% and will improve Quality of Life significantly.

Intervention

1. Physical Counterpressure Manoeuvres;

2. Midodrine.

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Eligibility criteria

Inclusion criteria

1. Clinical diagnosis of classical neurally- mediated reflex syncope, based on the medical history ór non-classical diagnosis of neurally-mediated reflex syncope and a positive tilt-table test;

2. 3 syncope episodes in the last 2 years;

3. Recognizable prodromal symptoms;

4. Age 18-70 years.

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, 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 < 1 year.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-01-2005
Enrollment:	300
Type:	Anticipated

Ethics review

Positive opinion

Date:	24-08-2005
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL112
NTR-old	NTR143
Other	: NHS 2003B156
ISRCTN	ISRCTN29932893

Study results

Summary results
N/A