Physical counterpressure manoeuvre trial.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25436

Source
NTR

Brief title
PC-Trial

Health condition

Vasovagal syncope.

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

Total burden of syncope recurrence (number of syncopal spells/year/patient).

Secondary outcome

1. Time to first recurrence;

2. Presyncope burden;

3. Quality of life.

Study description

Background summary

Physical counterpressure-manoeuvres have been reported as effective on controlling or aborting neurally mediated syncope.
In this trial we will study the long-term effects of these manoeuvres by randomising patients between conventional therapy or additional training in manoeuvres.

Study objective

In patients with syncope and and absence of significant structural heart disease physical counterpressure manoeuvres decrease the total syncope burden compared to standardized intensive conventional therapy.

Study design

N/A

Intervention

Physical counterpressure manoeuvres.

Contacts

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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 ór at least 1 syncopal spell in the last year and at least 3 episodes of presyncope in the last year;

3. Recognizable prodromal symptoms;

4. Age 16-70 years.

Exclusion criteria

1. Suspected or certain heart disease and high likelihood of cardiac syncope:

a. Syncope preceded by palpitations or precordial pain;

b. Syncope during exercise;

c. Heart failure;

d. Ejection fraction < 40%;

e. Old or recent myocardial infarction;

f. Hypertrophic cardiomyopathy;

g. Dilated cardiomyopathy;

h. Significant valvular disease;

i. Sinus bradycardia < 50 bpm or sino-atrial blocks;

j. Mobitz I second degree atrioventricular block;

k. Mobitz II 2nd or 3rd degree atrioventricular block;

l. Complete bundle branch block;

m. Rapid paroxysmal supraventricular tachycardia or ventricular tachycardia;

n. Pre-excited QRS complexes;

o. Prolonged QT interval;

p. Right bundle branch block pattern with ST-elevation in leads V1-V3 (Brugada syndrome);

q. Negative T waves in right precordial leads, epsilon waves and ventricular late potentials suggestive of arrhythmogenic right ventricular dysplasia).

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:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-01-2003
Enrollment:	200
Type:	Actual

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	NL107

Register	ID
NTR-old	NTR138
Other	: MEC 03/033
ISRCTN	ISRCTN45146526

Study results

Summary results

1. J Am Coll Cardiol. 2006 Oct 17;48(8):1652-7. Epub 2006 Sep 26.