Physical counterpressure manoeuvre trial.

Gepubliceerd: 24-08-2005 Laatst bijgewerkt: 18-08-2022

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.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25436

Bron
Nationaal Trial Register

Verkorte titel
PC-Trial

Aandoening

Vasovagal syncope.

Ondersteuning

Primaire sponsor: Academisch Medisch Centrum
Overige ondersteuning: N/A

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Physical counterpressure manoeuvres.

Contactpersonen

Publiek

Academic Medical Center (AMC),
Department of Internal Medicine,
P.O. Box 22660
W. Wieling
Meibergdreef 9
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5669111

Wetenschappelijk

Academic Medical Center (AMC),
Department of Internal Medicine,
P.O. Box 22660
W. Wieling

Meibergdreef 9
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5669111

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	05-01-2003
Aantal proefpersonen:	200
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	24-08-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL107

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

Resultaten

Samenvatting resultaten

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