

Physical Counterpressure manoeuvre trial

Submission date 06/12/2005	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 06/12/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 10/04/2008	Condition category Signs and Symptoms	☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr W Wieling

Contact details

Academic Medical Center
Department of Internal Medicine
Amsterdam
Netherlands
1105 AZ
+31 (0)20 566 9111
w.wieling@amc.uva.nl

Additional identifiers

Protocol serial number

MEC 03/033; NTR138

Study information

Scientific Title

Randomised trial of optimal conventional therapy versus optimal conventional therapy plus counterpressure manoeuvres in patients with neurally-mediated syncope

Acronym

PC-Trial

Study objectives

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

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised multi-centre, active controlled, parallel group, single blinded trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Vasovagal syncope

Interventions

Physical counterpressure manoeuvres compared to standardised intensive conventional therapy.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

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

Key secondary outcome(s)

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

Completion date

09/01/2005

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 two years or at least one syncopal spell in the last year and at least three episodes of presyncope in the last year

3. Recognisable prodromal symptoms

4. Aged 16 - 70 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

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

1.1. Syncope preceded by palpitations or precordial pain

1.2. Syncope during exercise

1.3. Heart failure

1.4. Ejection fraction less than 40%

1.5. Old or recent myocardial infarction

1.6. Hypertrophic cardiomyopathy

1.7. Dilated cardiomyopathy

1.8. Significant valvular disease

1.9. Sinus bradycardia less than 50 bpm or sino-atrial blocks

1.10. Mobitz I second degree atrioventricular block

1.11. Mobitz II 2nd or 3rd degree atrioventricular block

1.12. Complete bundle branch block

1.13. Rapid paroxysmal supraventricular tachycardia or ventricular tachycardia

1.14. Pre-excited QRS complexes

1.15. Prolonged QT interval

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

1.17. 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, transient ischemic 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 one year

Date of first enrolment

05/01/2003

Date of final enrolment

09/01/2005

Locations

Countries of recruitment

Netherlands

Study participating centre

Academic Medical Center

Amsterdam

Netherlands

1105 AZ

Sponsor information

Organisation

Academic Medical Center (AMC) (The Netherlands)

ROR

<https://ror.org/03t4gr691>

Funder(s)

Funder type

Charity

Funder Name

Netherlands Heart Foundation (Nederlandse Hartstichting) (The Netherlands) (ref: 2003B156)

Funder Name

Academic Medical Center (AMC) (The Netherlands)

Alternative Name(s)

Academic Medical Center, AMC

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location
Netherlands

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	17/10/2006		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes