# Physical Counterpressure manoeuvre trial

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

### Plain English summary of protocol

Not provided at time of registration

## Contact information

## Type(s)

Scientific

#### Contact name

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## 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)
- 1.1.7. 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

## 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