Physical Counterpressure manoeuvre trial

Submission date	Recruitment status	Prospectively registered
06/12/2005	No longer recruiting	☐ 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

Study website

http://pctrial.free.fr

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

05/01/2003

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

Age group

Adult

Sex

Both

Target number of participants

200

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

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)

Sponsor details

Meibergdreef 9 Amsterdam Netherlands 1105 AZ

Sponsor type

University/education

Website

http://www.amc.uva.nl

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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output typeDetailsDate createdDate addedPeer reviewed?Patient-facing?Results articleResults17/10/2006YesNo