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Physical Counterpressure manoeuvre trial

Submission date 06/12/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 06/12/2005	**Overall study status** Completed	
Last Edited 10/04/2008	**Condition category** 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

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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 type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	17/10/2006		Yes	No