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# Comparative study of two types of pacing for the treatment of unexplained syncope (vasovagal syndrome)

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 15/04/2010 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 23/07/2010 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 29/12/2020 | Signs and Symptoms | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
N/A

# Study information

## Scientific Title
Comparative study of two types of pacing for the treatment of unexplained syncope (vasovagal syndrome): a multicentre, single-blinded, randomised controlled trial with a direct individual benefit

## Study objectives
To compare the effectiveness of a dual chamber pacing (DDD) at 70 beats per minute (bpm) and a single chamber atrial pacing (AAI) at 30 bpm in patients suffering from vasovagal syndrome related to a predominant cardio-inhibitory reflex determined by adenosine-5'-triphosphate (ATP) test.

Null hypothesis:
The cumulative percentage syncope recurrence in the 30 bpm AAI-mode stimulated group, rp, equals that in the 70 bpm DDD-mode group, rw. Thus, rp=rw=r0.

Alternative hypothesis: rp=arw, where a =/= 1.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
1. The Ethics Committee of Poitiers University approved on the 1st of September 1999 (ref: 99.07.22)
2. Individual ethics committees of each clinical centre

## Study design
Prospective multicentre comparative randomised single blind study with a direct individual benefit

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet
Can be found at https://www.healthstudies.umn.edu/trc/en/en_protocol-2002-02-21.pdf (see pg. 15-16)

## Health condition(s) or problem(s) studied
Syncope (unknown origin)

### Interventions
ATP testing was carried out prior to randomisation. Only patients with block at least 10 seconds in duration were randomised to pacemaker implantation and programming with either:
1. Dual chamber pacing (DDD) at 70 bpm
2. Single chamber atrial pacing (AAI) at 30 bpm
An injection of adenosine triphosphate will be used to screen for cardiac pause.

The implantation is permanent, but the programming was set for the duration of the study to the random assignment. At the end of the study the recommended programming was to the more successful settings in the study, DDD @ 70bpm. The total follow-up was from January 2000 until May 2005.

### Intervention Type
Other

### Phase
Not Applicable

### Primary outcome measure
Recurrence of syncope

### Secondary outcome measures
1. Duration of cardiac pause
2. Reprogramming of pacemaker
3. Recurrences after reprogramming

### Overall study start date
01/07/2000

### Completion date
31/12/2005

## Eligibility

### Key inclusion criteria
1. Adult patients (greater than or equal to 18 years), agreeing to take part in the study and having signed the informed consent form
2. Patients having presented one or more episodes of syncope or pre-syncope unexplained by the usual screening tests: questionnaire, clinical examination, orthostatic hypotension investigation, biological tests, electrophysiological study (if necessary), echocardiogram (ECG), Holter, exercise test (optional), electroencephalogram (EEG) (optional), and brain scan (optional)
3. Negative sino-carotid massage (SCM)
4. Head-up tilt test conducted according to Appendix B protocol, whatever the result
5. Positive adenosine-5'-triphospate (ATP) test, confirmed by double reading by principal investigator

### Participant type(s)
Patient

### Age group

Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
200 patients (100 per group)

### Total final enrolment
80

### Key exclusion criteria
1. Syncope etiology revealed by usual screening testings
2. Positive SCM
3. Atrial or ventricular tachyarrhythmia
4. Defibrillator implanted (DAI)
5. Pacemaker previously implanted
6. Patient on waiting list for or having had heart transplantation
7. Sick sinus syndrome, brady-tachy syndrome
8. Atrial fibrillation, paroxysmal or permanent first and second-degree atrio-ventricular block, trifascicular block
9. Ongoing pregnancy. Women of childbearing age should be using reliable contraception.
10. Acute systemic infection or other surgical contra-indication for pacemaker implantation
11. Chronic obstructive bronchopneumopathy
12. Asthma
13. Diabetes

### Date of first enrolment
01/07/2000

### Date of final enrolment
31/12/2005

## Locations

### Countries of recruitment
Belgium

France

### Study participating centre
**Croix Rousse University Hospital**
Lyon
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# Sponsor information

### Organisation
Croix Rousse University Hospital (France)

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### Sponsor type
Hospital/treatment centre

### ROR
https://ror.org/006evg656

# Funder(s)

### Funder type
Industry

### Funder Name
Medtronic, Inc. (USA)

# 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 | 03/01/2012 | 29/12/2020 | Yes | No |