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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

Contact name
Dr Daniel Flammang

Contact details
Croix Rousse University Hospital
103 Grand Rue de la Croix Rousse
Lyon
France
69004
+33 (0)472 072865
daniel.flammang@yahoo.fr

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
France
69004

Sponsor information

Organisation
Croix Rousse University Hospital (France)

Sponsor details
Department of Cardiology
103 Grand Rue de la Croix Rousse
Lyon
France
69004
+33 (0)472 072865
daniel.flammang@yahoo.fr

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