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An investigation into the performance of the pacing mode AA1R (R) with respect to the percentage ventricular pacing and the evolution of atrial fibrillation when compared to the mode DDD (R) in patients with Sick Sinus Syndrome (SAFE PACE)

Submission date 29/09/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 29/09/2006	**Overall study status** Completed	
Last Edited 28/09/2011	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mrs Jane Eldridge

Contact details
Cardiac Catheter Lab
Hemel Hempstead General Hospital
Hillfield Road
Hemel Hempstead
United Kingdom
HP2 4AD
+44 01442 287364
jane.eldridge@whht.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0143162643

Study information

Scientific Title

Study objectives
Comparison of pacing modes AA1safe(R) R and DDD(R) in patients with Sick Sinus Syndrome.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval was received from the local medical ethics committee before trial recruitment began.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Cardiovascular: Sick Sinus Syndrome

Interventions
Retrospective, randomised, longitudinal study of the percentage ventricular pacing and the evolution of atrial fibrillation when compared to the mode DDD (R) in patients with Sick Sinus Syndrome

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Lower percentage of ventricular pacing and the amount of time spent in atrial fibrillation that occurs with each pacing mode

Secondary outcome measures
Not provided at time of registration

Overall study start date
15/04/2005

Completion date
31/12/2005

Eligibility

Key inclusion criteria
100 patients with Sick Sinus Syndrome

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
100

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
15/04/2005

Date of final enrolment
31/12/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Cardiac Catheter Lab
Hemel Hempstead
United Kingdom
HP2 4AD

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Hertfordshire Hospitals Research and Development Consortium (UK), NHS R&D Support Funding

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