

Cardiac pacing for the prevention of falls in carotid sinus hypersensitivity

Submission date 31/01/2002	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 31/01/2002	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 16/02/2009	Condition category Nervous System Diseases	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof RA Kenny

Contact details
Cardiovascular Investigation Unit
Ward 15 Offices
Royal Victoria Infirmary
Queen Victoria Road
Newcastle upon Tyne
United Kingdom
NE14 4AH
+44 (0)191 2225316
R.A.Kenny@ncl.ac.uk

Additional identifiers

Protocol serial number
PG/97098

Study information

Scientific Title

Study objectives

To determine:

1. The prevalence of unexplained or recurrent falls in cognitively normal adult accident and emergency attendees
2. The prevalence of carotid sinus hypersensitivity in those who fall
3. Whether cardiac pacing reduces the frequency of falls in a prospective series of patients with cardioinhibitory carotid sinus hypersensitivity

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Carotid sinus syndrome

Interventions

Cardiac pacemaker versus Thera rate drop responsive Medtronic Inc dual chamber pacemaker.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Added 16/02/2009:

Number of patients who fall in the 24 months following intervention.

Key secondary outcome(s)

Added 16/02/2009:

1. Frequency of falls
2. Dizzy symptoms and presyncope
3. Perceived health and mental status including informants perception and patients perception
4. Injury rates
5. Use of primary, secondary and tertiary care facilities
6. Length of hospital admission
7. Change in residential circumstances
8. Cognitive function

Completion date

01/10/1999

Eligibility

Key inclusion criteria

Added 16/02/2009:

1. Aged greater than or equal to 50 years, either sex
2. A minimum of two unexplained falls, +/- up to one syncope, in the previous 12 months
3. Mini Mental State Examination (MMSE) greater than 20/30
4. Sinus rhythm
5. Greater than 3 s asystole (upright or supine) during carotid sinus massage (CSM) (i.e. cardio-inhibitory carotid sinus hypersensitivity)
6. Gait, balance, and vision, as assessed by attending physician, not attributable cause of falls

Initial information at time of registration:

Patients with a history of unexplained falls with reproducible cardio-inhibitory or mixed carotid sinus hypersensitivity

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

Added 16/02/2009:

1. Contraindication to CSM
2. Atrial fibrillation
3. Medications which enhance vagal activity
4. Neoplasm
5. Chronic renal failure
6. Chronic liver disease
7. Heart failure (New York Heart Association [NYHA] class III/IV)

Date of first enrolment

01/10/1998

Date of final enrolment

01/10/1999

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
Cardiovascular Investigation Unit
Newcastle upon Tyne
United Kingdom
NE14 4AH

Sponsor information

Organisation
British Heart Foundation (UK)

ROR
<https://ror.org/02wdwnk04>

Funder(s)

Funder type
Charity

Funder Name
British Heart Foundation (UK)

Alternative Name(s)
The British Heart Foundation, the_bhf, BHF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

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	01/03/2009		Yes	No
Protocol article	protocol/initial results	01/01/1999		Yes	No