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The use of biphasic energy for cardioversion of atrial fibrillation under midazolam sedation. A comparison of results using monophasic and biphasic energies with short acting general anaesthesia (GA) and midazolam sedation

Submission date 12/09/2003	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 25/09/2013	**Condition category** Circulatory System	

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
N0211114381

Study information

Scientific Title

Study objectives
To compare side effects of using higher traditional cardioverters with biphasic cardioversion.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Cardiovascular: Atrial fibrillation (AF)

Interventions
Group 1 - Monophasic direct current cardioversion (DCCV) with midazolam sedation
Group 2 - Biphasic DCCV with midazolam sedation
Group 3 - Monophasic DCCV with short acting GA (propofol)
Group 4 - Biphasic DCCV with short acting GA (propofol)

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)

Midazolam

Primary outcome measure
1. Side effects of higher energy
2. Efficacy
3. Patient tolerance
4. Quantity of drugs
5. Length of stay in hospital (day case)

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/12/2001

Completion date
28/06/2003

Eligibility

Key inclusion criteria
Adults with atrial fibrillation

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/12/2001

Date of final enrolment
28/06/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Surrey County Hospital NHS Trust
Guildford, Surrey
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GU2 7XX

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
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SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
Royal Surrey County Hospital NHS Trust (UK)

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