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Safety and efficacy of procainamide and amiodarone in the treatment of atrial fibrillation of recent onset

Submission date 23/02/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 08/03/2006	**Overall study status** Completed	
Last Edited 25/09/2009	**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
N/A

Study information

Scientific Title

Study objectives
To study whether procainamide and amiodarone are both effective after digoxin administration to restore sinus rhythm

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the University
of Athens on 4/5/1998, reference number 78/1998

Study design
Randomised double-blind 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
Atrial fibrillation

Interventions
After administration of digitalis (digoxin), and in case of failure to restore Sinus Rhythm (SR), the patients were randomized into two groups. Randomization was performed with the use of sealed envelopes, thus guaranteeing an almost equal number of patients.
Group A (113 patients) received amiodarone intravenously 300 mg in 30 minutes and in case of failure to restore SR, amiodarone was continued for a further 24 hours as an intravenous infusion (maintenance) of 20 mg/kg.
Group B (110 patients) were administered a bolus dose of 1 g intravenous procainamide, and in the case of failure to restore sinus rhythm in 30 minutes, 2 mg/min (maintenance) for the next 24 hours. The other two participants decided to be treated privately, therefore both received digitalis and the study medication, but did not stay in the NHS long enough to be included in the study.

Intervention Type

Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Procainamide, amiodarone and digoxin

Primary outcome measure
Restoration of sinus rhythm

Secondary outcome measures
1. Time of cardioversion
2. Blood pressure fluctuations

Overall study start date
05/05/1998

Completion date
20/08/2003

Eligibility

Key inclusion criteria
Atrial fibrillation of recent onset (less than 24 hours)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
225

Key exclusion criteria
1. Age <18 years
2. Baseline systolic blood pressure <100 mmHg
3. Known thyroid disease
4. Serum potassium <3.5 mmol/l
5. Pre-treatment with any anti-arrhythmic drug
6. Documented permanent AF, atrial flutter and a corrected heart rate (QTc) interval >440 msec

Date of first enrolment
05/05/1998

Date of final enrolment

20/08/2003

Locations

Countries of recruitment
Greece

Study participating centre
15B Agiou Thoma street
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11527

Sponsor information

Organisation
Greek National Health Service (Greece)

Sponsor details
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Sponsor type
Government

Funder(s)

Funder type
Government

Funder Name
Greek National Health Service (Greece)

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	01/08/2007		Yes	No