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Intravenous and oral administration of amiodarone for the management of recent onset atrial fibrillation (AF): a randomized, digoxin and disopyramide controlled trial

Submission date 05/02/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 07/03/2006	**Overall study status** Completed	
Last Edited 18/02/2008	**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 confirm if oral amiodarone is as effective as intravenous amiodarone in restoring sinus rhythm in patients with recent AF.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Provided by the Ethics Committee of the Medical School of the University of Athens on 12/03 /1999.

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Atrial fibrillation

Interventions
All patients, a total number of 338 received digoxin and disopyramide and if this restored sinus rhythm within two hours, they were excluded from the study.
Patients were randomized into two groups. One group received intravenous amiodarone and the other group received oral amiodarone.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
amiodarone

Primary outcome measure
Restoration of sinus rhythm

Secondary outcome measures
Blood pressure monitoring

Overall study start date
24/04/1999

Completion date
30/12/2004

Eligibility

Key inclusion criteria
Patients with recent onset atrial fibrillation

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
223

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 antiarrhythmic drug
6. Documented permanent AF
7. Atrial flutter and corrected heart rate (QTc) interval >440 msec
8. The duration of tachyarrhythmia estimated by medical history
9. The current guidelines regarding prevention of thromboembolism are also followed

Date of first enrolment
24/04/1999

Date of final enrolment
30/12/2004

Locations

Countries of recruitment
Greece

Study participating centre
15B Agiou Thoma street
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Sponsor information

Organisation
Greek National Health Service (Greece)

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Sponsor type
Government

Funder(s)

Funder type
Government

Funder Name
Greek National Health Service

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	18/10/2007		Yes	No