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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

Registration date
07/03/2006

Last Edited
18/02/2008

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Theodoros Xanthos

Contact details
15B Agiou Thoma street
Athens
Greece
11527
+30 (0)2107462550
theodorosxanthos@yahoo.com

Additional identifiers

Protocol serial number
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

Study type(s)
Not Specified

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(s)
Restoration of sinus rhythm

Key secondary outcome(s))
Blood pressure monitoring

Completion date
30/12/2004

Eligibility

Key inclusion criteria
Patients with recent onset atrial fibrillation

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
Athens
Greece
11527

Sponsor information

Organisation
Greek National Health Service (Greece)

Funder(s)

Funder type
Government

Funder Name
Greek National Health Service

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	18/10/2007		Yes	No