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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

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## Additional identifiers

## 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
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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 |