

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 08/03/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 25/09/2009	Condition category Circulatory System	<input type="checkbox"/> 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
theodorosxanthos@yahoo.com

Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

Restoration of sinus rhythm

Key secondary outcome(s)

1. Time of cardioversion
2. Blood pressure fluctuations

Completion date

20/08/2003

Eligibility

Key inclusion criteria

Atrial fibrillation of recent onset (less than 24 hours)

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 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

Athens

Greece

11527

Sponsor information

Organisation

Greek National Health Service (Greece)

Funder(s)**Funder type**

Government

Funder Name

Greek National Health Service (Greece)

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	01/08/2007		Yes	No