

Angiotensin II-Antagonist in Paroxysmal Atrial Fibrillation Trial

Submission date 01/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 04/10/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 30/10/2008	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

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Additional identifiers

Protocol serial number
AF NET B10

Study information

Scientific Title

Acronym

ANTIPAF

Study objectives

Blocking the angiotensin II type 1 receptor reduces the incidence of episodes of atrial fibrillation in patients with paroxysmal atrial fibrillation during 12 months by more than 25% compared to standard medication without angiotensin II type 1 receptor.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Paroxysmal Atrial Fibrillation

Interventions

Examination of the study hypothesis in a prospective, randomized, placebo-controlled, double-blind group comparison in patients with documented paroxysmal atrial fibrillation.

40 mg/day Olmesartanmedoxomil versus Placebo.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Angiotensin II-Antagonist

Primary outcome(s)

Percentage of days with documented episodes of paroxysmal atrial fibrillation (number of days with paroxysmal atrial fibrillation/number of days with at least one readable Tele-ECG recording)

Key secondary outcome(s))

1. Time to first occurrence of a documented relapse of atrial fibrillation
2. Time to first occurrence of a symptomatic documented episode of AF
3. Time to persistent atrial fibrillation
4. Time to prescription of the recovery-medication
5. Number of hospitalizations for cardiovascular reasons (-> Endpoint review)

6. Number of intermediate medical visits for cardiovascular reasons (-> Endpoint review) without hospitalization
7. Number of cerebrovascular events
8. Quality of life

Completion date

30/11/2007

Eligibility

Key inclusion criteria

1. Documented paroxysmal atrial fibrillation: electrocardiogram (ECG) documentation of atrial fibrillation at least in one ECG recorded during the last 2 months prior to randomization plus additional ECG recording of sinus rhythm at least 12 hours after the above mentioned ECG documentation
2. Age ≥ 18
3. Patient informed orally and in writing
4. Written informed consent of the patient

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Strong clinical evidence for therapy with AT II/ACE inhibitors within the last month
2. Therapy with antiarrhythmic agents of class I or class III within the last month, therapy with amiodaron within the last 3 months
3. DC cardioversion within the last 3 months
4. Symptomatic bradycardia
5. Implanted pacemaker or implanted cardioverter/defibrillator with any antitachycardiac algorithm in use
6. Cardiac surgery or cardiac catheter ablation within the last 3 months
7. Typical angina pectoris symptoms at rest or during exercise
8. Known coronary artery disease with indication for intervention
9. Valvular disease >II degree
10. Left ventricular ejection fraction <40%
11. Diastolic blood pressure >110 mmHg at rest

- 12. Symptomatic arterial hypotension
- 13. Known renal artery stenosis
- 14. Serum creatinine >1.8 mval/l

Date of first enrolment

27/01/2005

Date of final enrolment

30/11/2007

Locations

Countries of recruitment

Germany

Study participating centre

University Hospital Magdeburg

Magdeburg

Germany

39120

Sponsor information

Organisation

German Atrial Fibrillation Network

ROR

<https://ror.org/01spm3d88>

Funder(s)

Funder type

Research organisation

Funder Name

German AF Network, Grant No 01GI0204 (Germany)

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	01/04/2007		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes