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Angiotensin II-Antagonist in Paroxysmal Atrial Fibrillation Trial

Submission date	Recruitment status	[_] Prospectively registered
01/09/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/10/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
30/10/2008	Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.kompetenznetz-vorhofflimmern.de

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
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)

Secondary outcome measures
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

Overall study start date
27/01/2005

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
422

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

Sponsor details

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Sponsor type
Research organisation

Website
http://www.kompetenznetz-vorhofflimmern.de

ROR
https://ror.org/01spm3d88

Funder(s)

Funder type
Research organisation

Funder Name
German AF Network, Grant No 01GI0204 (Germany)

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	01/04/2007		Yes	No