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BACE-PACE-Trial - A multicenter study to investigate preventive pacing in combination with antiarrhythmic beta-blocker or AT-I-/angiotensin converting enzyme (ACE)-inhibitor therapy on the recurrence of atrial fibrillation (AF) in patients with dual-chamber pacemakers

Submission date 21/08/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 12/10/2005	**Overall study status** Completed	
Last Edited 28/10/2021	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
German Atrial Fibrillation Network B05

Study information

Scientific Title
BACE-PACE-Trial - A multicenter study to investigate preventive pacing in combination with antiarrhythmic beta-blocker or AT-I-/angiotensin converting enzyme (ACE)-inhibitor therapy on the recurrence of atrial fibrillation (AF) in patients with dual-chamber pacemakers

Acronym
BACE PACE

Study objectives
Comparison of AF-Burden in patients with paroxysmal atrial fibrillation (AF) and the necessity of a Dual-Chamber-Pacemaker-Therapy either with a DDD[R]60-Stimulation or AF prevention pacing. All Patients were stratified according to their existing drug therapy e.g. Beta-Blocker or ACE-Inhibitor.

Aim of the trial is to prove the inferiority concerning the efficacy of preventive pacing stimulation (PS) versus DDD[R]60-Standard stimulation (ST). Therefore AF burden at baseline is compared with both study groups. Responder is a AF patient with a relative AF burden >25% or absolute >1%, whereas the AF Burden at baseline phase must be greater than 1%.

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)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Atrial fibrillation

Interventions
Participants are randomised either to preventive pacing stimulation or to DDD[R]60-Stimulation. Implantation of a triggered prevention pacemaker (Vitatron Selection 9000, Prevent AF, T 70 DR) 2-4 months before inclusion in the trial.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Total of patients with a significant reduction (>25%) of AF burden in the 6-months-follow-up-period

Secondary outcome measures
1. AF Burden
2. Total of patients without AF recurrence
3. Efficacy of pharmacologic treatment in preventive stimulation
4. Time in sinus rhythm
5. Time until first AF recurrence
6. Onset-Mechanism with and without medication
7. Total of patients who have a benefit from preventive stimulation
8. Proportion of atrial and ventricular stimulation
9. Safety of the therapy

Overall study start date
01/02/2005

Completion date
31/03/2007

Eligibility

Key inclusion criteria
1. Idiopathic paroxysmal symptomatic atrial fibrillation
2. Implantation of a fully functional pacemaker (e.g. normal impedance, stimulation thresholds and sensing values) Vitatron Selection 9000, Prevent AF, T 70 DR 2-4 months ago, because of one of the following indications: symptomatic sinus bradycardia, sinus arrest, Tachy-Brady-Syndrome
3. Symptomatic sinuatrial block
4. High-grade AV-Block (AV Block II und III)
5. Binodal disease: Sick-Sinus-Syndrome and high-grade AV-Block
6. AV-Nodal-Ablation in combination with a pacemaker therapy ('Ablate & Pace')
7. Written informed consent of the patient
8. Age >18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
224 patients

Key exclusion criteria
1. Chronic heart failure (New York Heart Association [NYHA] III/IV)
2. Acute myocardial infarction <6 months
3. Hypertrophic obstructive cardiomyopathy
4. Symptomatic hypo- or hyperthyreosis
5. Instable angina pectoris
6. Cardiogenic shock
7. Patients with diabetes mellitus and recurrence of hypoglycaemia
8. Pregnancy or breast feeding
9. Participation in a clinical trial within the last 30 days. Simultaneous participation in a registry (e. g. project AB1 of the AFNET) is permitted.
10. Reduced life expectancy (<6 months)
11. Legal incapacity, or other circumstances which would prevent the patient from understanding the aim, nature or extent of the clinical trial
12. Evidence of an uncooperative attitude

Date of first enrolment
01/02/2005

Date of final enrolment
31/03/2007

Locations

Countries of recruitment
Germany

Study participating centre
University Heart Center
Hamburg
Germany
20246

Sponsor information

Organisation
German Atrial Fibrillation Network

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Sponsor type
Research organisation

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

ROR
https://ror.org/01spm3d88

Funder(s)

Funder type
Industry

Funder Name
German Atrial Fibrillation Network (Germany)

Funder Name
Vitatron GmbH (Germany)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		31/12/2008	28/10/2021	Yes	No