

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 ☒ Protocol
Registration date 12/10/2005	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 28/10/2021	Condition category Circulatory System	☐ Individual participant data ☐ Record updated in last year

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
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

Study type(s)

Prevention

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

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

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