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

**Plain English summary of protocol**Not provided at time of registration

# **Contact information**

Type(s)

Scientific

Contact name

**Prof Andreas Schuchert** 

### Contact details

University Heart Center
Martinistr. 52
Hamburg
Germany
20246
+49 40 42803 5304
schuchert@uke.uni-hamburg.de

## 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

### Sponsor details

Domagkstrasse 11 Münster Germany 48149 +49 251 83 45340 Thomas.Weiss@ukmuenster.de

### 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