Trial Description

Title

High-Intensity Interval Training prior to Pulmonary Vein Ablation in the Treatment of Atrial Fibrillation – a prospective, randomized controlled trial: Prehabilitation Study of the Cologne ExAfib Trial

Trial Acronym

ExAfib-Prehab

URL of the trial

http://n.a.

Brief Summary in Lay Language

The Ablation of the pulmonary veins is an established therapy for atrial fibrillation. We are studying, whether exercise in the weeks prior to the ablation will improve the results.

Brief Summary in Scientific Language

The aim of the study is to analyze, whether a high-intensity-training-programme in the weeks before a pulmonary vein isolation by cryo-balloon will improve outcomes in patients with atrial fibrillation.

Do you plan to share individual participant data with other researchers?

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00017836**
- Date of Registration in DRKS: **2019/08/19**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **049/2019 , Deutsche Sporthochschule Köln / German Sport university Cologne**

Secondary IDs

Health condition or Problem studied

- ICD10: **I48.0 - Paroxysmal atrial fibrillation**

Interventions/Observational Groups

- Arm 1: **High-intensity interval training on the stationary bike twice per week for 3 months, supervised by sports scientists and sports physicians.**
- Arm 2: **Guideline-recommendation regarding physical activity**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Control group receives no treatment**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **II**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

Freedom from atrial fibrillation: time to ECG-documented recurrence

Burden of atrial fibrillation: episodes documented during Holter-ECG and questionnaire

Data collection T0 (pre exercise intervention) T1 (3 months after ablation) T2 (12 months after ablation).

Secondary Outcome

Safety and Feasibility
PVI-associated complications
Physical fitness (VO2peak and strength)

Muscle strength
Subjective quality of life (SF-36)
Major adverse cardiovascular events (MACE): Stroke, myocardial infarction, death from cardiovascular cause
Minor adverse events
Adherence rate
AF-associated hospitalization
Body composition
inflammatory markers (CRP, Interleukins)
Collagen turnover markers
Cardiac function (echocardiography incl. strain analysis)
Blood pressure (24h)
Arterial stiffness (pulse wave analysis)
Heart rate (24h: min, max, average)
HRV (in sinus rhythm)
Muscle hypertrophy (diameter of Vastus lateralis)

Data collection T0 (pre exercise intervention) T1 (3 months after ablation) T2 (12 months after ablation).

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Krankenhaus Porz am Rhein, Köln**
- other **German Sports University Cologne, Köln**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2019/08/20**
- Target Sample Size: **60**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **40 Years**
- Maximum Age: **80 Years**

Additional Inclusion Criteria

- Male and female patients

- between the ages of 40 and 80 years
- symptomatic paroxysmal atrial fibrillation (EHRA ≥ 2)

Exclusion criteria

< 40 or > 80 years of age
- significant limitation to the exercise of the intervention-arms
- BMI ≥ 35
- participation in regular aerobic or resistance exercise training in the last 6 months (> 60 minutes/week)
- previous open heart surgery
- left ventricular ejection fraction < 40% during sinus rhythm
- significant valve disease
- implanted cardiac pacemaker, ICD or resynchronization therapy
- coronary artery disease without complete revascularization
- unstable Angina
- uncontrolled arrhythmias causing unstable conditions
- uncontrolled hypertension
- uncontrolled Diabetes mellitus
- prior pulmonary vein ablation

Addresses

■ **Primary Sponsor**

Deutsche Sporthochschule Köln
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■ **Contact for Scientific Queries**

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Sources of Monetary or Material Support

- **Institutional budget, no external funding (budget of sponsor/PI)**

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URL: **[---]***

Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

** This entry means the parameter is not applicable or has not been set.*
**** This entry means that data is not displayed due to insufficient data privacy clearing.*