

Pulmonary Vein Isolation using Robotic navigation: a prospective randomised trial with invasive follow-up

Submission date 27/01/2008	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 29/08/2008	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 29/08/2008	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
RN/2

Study information

Scientific Title

Acronym

RoboticPVI

Study objectives

Non-inferiority trial of robotic navigation (RN) guided pulmonary vein isolation compared to manually steered catheter approach.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Hamburg Ethics Committee on the 5th May 2008 (ref: 2801 /2008).

Primary study design

Interventional

Study design

Prospective randomised non-blinded clinical trial

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Atrial Fibrillation

Interventions

Catheter ablation with cooled tip electrode with conduction block of all 4 vein proven by circumferential mapping catheter.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Recovery of any pulmonary veins (PVs), measured after a follow up of one year is completed.

Key secondary outcome(s)

Peri-/post-procedural complications.

Completion date

03/01/2008

Eligibility

Key inclusion criteria

1. Documented, symptomatic atrial fibrillation lasting less than 48 hours
2. No prior history of electrical cardioversion
3. Both genders aged from 18 - 70 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Left Atrial (LA) diameter greater than 60 mm
2. Refuse to give written informed consent
3. Non-eligibility for interventional therapy

Date of first enrolment

12/01/2007

Date of final enrolment

03/01/2008

Locations**Countries of recruitment**

Germany

Study participating centre

Martinistr. 52

Hamburg

Germany

20249

Sponsor information**Organisation**

University Heart Center Hamburg (Germany)

ROR

<https://ror.org/01zgy1s35>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration