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

Submission date	Recruitment status	[ ] Prospectively registered
27/01/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
29/08/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
29/08/2008	Circulatory System	[ ] 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).

Study design
Prospective randomised non-blinded clinical trial

Primary study design
Interventional

Study type(s)
Diagnostic

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

Interventions
Catheter ablation with colled 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-elegibility 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