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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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Secondary outcome measures
Peri-/post-procedural complications.

Overall study start date
12/01/2007

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
50

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)

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.uke.uni-hamburg.de/zentren/herz/index.php

ROR
https://ror.org/01zgy1s35

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded (Germany)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration