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Quality of life before and after atrial fibrillation ablation

Submission date
23/02/2022

Recruitment status
No longer recruiting

Registration date
28/02/2022

Overall study status
Completed

Last Edited
28/02/2022

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Atrial fibrillation (AF) is a heart condition that causes an irregular and often abnormally fast heart rate. Ablation of AF is an alternative to drug treatment. Ablation is where the area inside the heart that's causing the abnormal heart rhythm is destroyed using radiofrequency energy. Gender differences in symptoms and perceived health-related quality of life (HRQOL) in patients with AF have been reported previously. Women experience a lower HRQOL, faster heart rate, and more symptoms such as palpitations (heart pounding or racing) and dyspnea (breathing difficulties) than men. Furthermore, they experience worse physical functioning independently of other heart diseases or age. Despite more symptoms, women are less often referred for cardioversion and ablation of atrial fibrillation. The aim of this study is to evaluate symptoms, morbidity (illness), referral patterns, experience of the information given, functional impairment, HRQOL, and perceived improvement from a gender perspective in patients with AF before and 6 months after ablation.

Who can participate?
Patients aged over 18 years referred for atrial fibrillation ablation

What does the study involve?
Questionnaires and data from the patient’s file are used to investigate quality of life, symptoms and referral experiences before AF ablation and 6 months after ablation.

What are the possible benefits and risks of participating?
There are benefits or risks for the participant.

Where is the study run from?
Karolinska Hospital (Sweden)

When is the study starting and how long is it expected to run for?
January 2011 to July 2016

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Carina Carnlöf
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Contact information

Type(s)
Principal Investigator

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Women with atrial fibrillation improve more than men at 6 months follow-up after pulmonary vein isolation

Study objectives
This study evaluates referral patterns and symptoms, morbidity, functional impairment, and health-related quality of life (HRQOL) from a gender perspective in patients with atrial fibrillation (AF) before and 6 months after pulmonary vein isolation (PVI).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/02/2012, Regional Institutional Ethics Committee (Regionala Etikprövningsmyndigheten, Tomtebodavägen 18A, 171 65 Stockholm, Sweden; +46 (0)8 524 8000; registrator@etikprovningen.se), ref: 2011/1903-31/2

Study design
Single-center cohort study with a prospective design

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use contact details to request participants information sheet

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

Interventions
The study is a single-center cohort study with a prospective design using different questionnaires at baseline to investigate quality of life (QoL), symptoms and referral experiences before atrial fibrillation ablation with a follow-up of QoL and symptoms at 6 months post ablation.

Intervention Type
Other

Primary outcome measure
1. Symptoms measured using the Symptom Checklist-Frequency and Severity Scale (SCL) at baseline and 6 months
2. QoL measured using the Short Form-36 (SF-36) health survey questionnaire at baseline and 6 months
3. Functional impairment measured using the Sick Impact Profile at baseline and 6 months

Secondary outcome measures
Referral history, experience of information given in regard to the arrhythmia, number of years with symptomatic atrial fibrillation (AF), and previous evaluations and diagnoses of their arrhythmia symptoms, measured with a supplementary questionnaire at baseline

Overall study start date

01/01/2011

Completion date
12/07/2016

Eligibility

Key inclusion criteria
Patients referred for a de novo PVI

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
240

Total final enrolment
240

Key exclusion criteria
1. Inability to read or understand Swedish
2. Cognitive impairment

Date of first enrolment
21/02/2013

Date of final enrolment
12/01/2016

Locations

Countries of recruitment
Sweden

Study participating centre
Karolinska University Hospital
Heart, Vascular & Neurology Theme
M97
Stockholm
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141 86

Sponsor information

Organisation
Karolinska Institute

Sponsor details
Hälsovägen
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Sponsor type
University/education

Website
http://ki.se/en/startpage

ROR
https://ror.org/056d84691

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal. Additional files will be available upon request. The protocol and participant information sheet are written in Swedish.

Intention to publish date
01/04/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Carina Carnlöf (carina.carnlof@regionstockholm.se). All patients gave

their written consent, and all data are logged in a dataset in SPSS. The dataset is anonymised with a study number.

IPD sharing plan summary

Available on request