

Quality of life before and after atrial fibrillation ablation

Submission date 23/02/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/02/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 28/02/2022	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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
carina.carnlof@regionstockholm.se

Contact information

Type(s)

Principal investigator

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Quality of life

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(s)

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

Key secondary outcome(s)

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

Completion date

12/07/2016

Eligibility

Key inclusion criteria

Patients referred for a de novo PVI

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

Sweden

141 86

Sponsor information

Organisation

Karolinska Institute

ROR

<https://ror.org/056d84691>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

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