

# Quality of life before and after atrial fibrillation ablation

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<b>Registration date</b> 28/02/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 28/02/2022	<b>Condition category</b> 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

Mrs Carina Carnlöf

### ORCID ID

<https://orcid.org/0000-0001-5964-0393>

### Contact details

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## Additional identifiers

### Clinical Trials Information System (CTIS)

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](mailto: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