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How common are diabetes and prediabetes in people with atrial fibrillation?

Submission date
27/08/2023

Recruitment status
No longer recruiting

Registration date
30/08/2023

Overall study status
Ongoing

Last Edited
13/11/2024

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Type 2 diabetes is a big health problem. Around half of the people who have diabetes don't even know they have it. Finding diabetes early and treating it can really help stop bad things from happening because of the disease.

In the past, scientists found out that many people who had heart attacks also had diabetes or a condition that's like a warning sign for diabetes. Almost two-thirds of people with heart attacks had either new type 2 diabetes or this warning sign, which is called impaired glucose tolerance. But we're not sure if this is the same for people with a heart condition called atrial fibrillation.

So, we're doing this study to figure out how common it is for people with atrial fibrillation to have diabetes or this warning sign for diabetes that we talked about. If we find out that a lot of them do have these glucose problems, it could change how we take care of these patients. Maybe we'll start checking everyone with atrial fibrillation for glucose problems, like we do for people with heart attacks.

Also, we want to see if finding these glucose problems later affects how well a treatment called electrical cardioversion works for people with atrial fibrillation. We're also checking if it makes it more likely for atrial fibrillation to come back or for other heart problems to happen.

Who can participate?
Patients with atrial fibrillation undergoing electrical cardioversion at the Cardiology Department, Danderyd University Hospital who are under 80 years old and have no previous known diabetes.

What does the study involve?
The participants in this study will have an additional appointment at the Cardiology Department following the electrical cardioversion procedure. During this visit, their medical history will be documented and screening for glucose abnormalities will be conducted. The screening involves obtaining a blood sample to assess levels of glycated haemoglobin A1c (HbA1c) and performing an oral glucose tolerance test (OGTT). For the OGTT, a morning blood sample is taken after an overnight fast, followed by another blood sample 2 hours after consuming a sugary drink.

Additionally, blood samples will be collected to analyse various risk markers for cardiovascular disease. Moreover, an echocardiogram will be performed to assess the cardiac function. This comprehensive visit is expected to last approximately 2.5 to 3 hours.

What are the possible benefits and risks of participating?
There are no specific risks involved in participating in this study. A potential benefit is that the results of the blood tests can lead to an earlier initiation of treatment for previously undiagnosed glucose abnormalities.

Where is the study run from?
Cardiology Department, Danderyd University Hospital (Sweden)

When is the study starting and how long is it expected to run for?
October 2017 to October 2028.

Who is funding the study?
Region Stockholm and Stiftelsen Hjärtat (Sweden)

Who is the main contact?
Dr. Pia Lundman, pia.lundman@ki.se

Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2017/1878-31/2

Study information

Scientific Title
Early Detection of Glucose Abnormalities in Atrial Fibrillation

Acronym
EDGA-AF

Study objectives
To study the prevalence of previously undiagnosed diabetes and prediabetes in individuals with atrial fibrillation undergoing electrical cardioversion and investigate the prognostic importance of these glucose abnormalities in this group of patients.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 25/10/2017, Regional Ethical Review Board in Stockholm (Tomtebodavägen 18A, plan 3, Solna, Stockholm, 17165, Sweden; +46 8-52487000; kansli@stockholm.epn.se), ref: 2017/1878-31/2

Study design
Single-center observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)

Hospital

Study type(s)
Screening

Participant information sheet
Not available in web format please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Prevalence and prognostic importance of previously undiagnosed glucose abnormalities in patients with atrial fibrillation.

Interventions
Study participants (individuals with atrial fibrillation undergoing electrical cardioversion) will be screened for previously undiagnosed glucose abnormalities with a glycated haemoglobin A1c (HbA1c) and a standardised 75-g oral glucose tolerance test (OGTT). Depending on the result of the screening, the study participants will be divided in 3 groups (normal glucose metabolism, prediabetes, diabetes) and followed prospectively for recurrence of atrial fibrillation and for the incidence of death or hospitalization for other cardiovascular disease, such as myocardial infarction, stroke, heart failure. Baseline differences in the echocardiographic and electrocardiographic findings and differences in biochemical variables, such as troponin, pro-BNP, and markers of inflammation and fibrosis, between patients with normal and abnormal glucose metabolism will also be analyzed and described.

Intervention Type
Other

Primary outcome measure
Prevalence of previously undiagnosed diabetes and prediabetes measured at baseline using the recorded values of plasma glucose (fasting or 2-hour value after the Oral Glucose Tolerance Test) or HbA1c according to the criteria set forth by the World Health Organisation (WHO) and American Diabetes Association (ADA).

Secondary outcome measures
1. Recurrence of atrial fibrillation after successful electrical conversion after three months and twelve months, respectively measured using patient records
2. Recurrence of atrial fibrillation or hospitalisation for other cardiovascular disease, such as myocardial infarction, stroke, heart failure and occurrence of death over 3 years measured using patient records
3. Echocardiographic and electrocardiographic findings at inclusion measured by performing a standardised adult transthoracic echocardiography examination and by registering a standard 12-lead electrocardiogram (ECG)
4. Biochemical variables, such as troponin, pro-BNP, and markers of inflammation and fibrosis at inclusion measured by analysis of plasma venous samples in an accredited laboratory

Overall study start date
25/10/2017

Completion date
01/10/2028

Eligibility

Key inclusion criteria
Individuals with atrial fibrillation undergoing electrical cardioversion

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
300

Key exclusion criteria
1. Diabetes mellitus type 1
2. Stage 4 or 5 CKD (GFR<30 ml/min, dialysis).
3. Malignant tumor under treatment (or metastatic cancer) with life expectancy <12 months.
4. Thyrotoxicosis
5. Acute infection and/or chronic inflammatory disease (with highly elevated inflammatory markers and/or ongoing steroid therapy).
6. Advanced COPD (e.g. treatment with steroids).
7. Conditions that complicate participation in the study as assessed by the treating physician or the study investigators.

Date of first enrolment
18/10/2018

Date of final enrolment
13/06/2024

Locations

Countries of recruitment
Sweden

Study participating centre

Cardiovascular laboratory, KFC
Danderyd University Hospital
Entrévägen 2
Stockholm
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Sponsor information

Organisation
Stockholm County Council

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Sponsor type
Government

Website
http://www.sll.se/om-landstinget/Information-in-English1/

ROR
https://ror.org/02zrae794

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Sponsor type
University/education

Website

https://ki.se/kids

ROR
https://ror.org/056d84691

Funder(s)

Funder type
Government

Funder Name
Stockholms Läns Landsting

Alternative Name(s)
Stockholm County Council

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Sweden

Funder Name
Stiftelsen Hjärtat

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/10/2029

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from the principal investigator of the study.
pia.lundman@ki.se

IPD sharing plan summary
Available on request