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The RedHeart Study. ECG recording with the Coala Heart Monitor in patients with symptomatic palpitations – underlying arrhythmias and effects on symptoms and quality of life

Submission date
29/10/2019

Recruitment status
No longer recruiting

Registration date
04/11/2019

Overall study status
Completed

Last Edited
22/02/2021

Condition category
Circulatory System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Palpitations are common symptoms. It simply implies the feeling of heartbeats and the causes are many. The findings are considered usually benign and may be due to changes in the autonomic tone of the heart (mental stress or physical exertion, pregnancy) or benign so-called extra beats. They occur in all individuals to varying degrees, but the majority is not aware of them. Palpitations may also be a symptom of diseases such as high blood pressure, thyroid toxicity or other metabolic disorders. Palpitations are sometimes caused by clinically significant arrhythmias such as atrial fibrillation (AF) or other paroxysmal supra-ventricular arrhythmias and to a lesser extent ventricular arrhythmia. It is a common belief that there is an under detection of clinically significant arrhythmias like AF. Whatever the cause, palpitations can result in pronounced worries and anxiety and the extent and prevalence of this is unknown. The mental symptoms are usually rooted in a concern for underlying serious heart disease. Recent research has revealed sex differences in the appearance of rhythm disturbances as well as differences in pathology, symptoms and treatment. Women with arrhythmias are more often misdiagnosed and under treated both with invasive treatment and with drug treatment compared with men. It is often difficult with traditional ECG recording technology (Holter registration where the ECG is continuously recorded over one to several days) to catch episodes of palpitations, which usually occur sporadically. Nowadays, new technologies offer efficient personal controlled ECG recording, which can be used for extended periods of time and in a daily life setting. The possibility to record ECG in connection with symptoms is hereby increased. Furthermore, getting a rapid response on a smartphone about the ECG findings makes it possible to provide adequate and calming information, or in some cases give a correct arrhythmia diagnosis and suggest adequate therapy. This, in turn, should be a good prerequisite to reduce the mental health problems caused by palpitations and thereby improve the individual's quality of life and to reduce visits to doctors and hospitals.
This study aims to answer the following questions:

1. To what extent do heart palpitations induce anxiety, worries, and reduce quality of life?
2. To what extent will a patient managed ECG monitoring system document underlying heart rhythm when having paroxysmal palpitations?
3. Is there a correlation between the prevalence of arrhythmias and mental symptoms and quality of life?
4. If getting instant feedback on the ECG rhythm, will that decrease mental symptoms and/or increase quality of life?

Who can participate?
Women aged over 18 with symptomatic palpitations

What does the study involve?
At the start and the end of the study the participants answer questionnaires about the following:
1. Age, frequency of symptoms, if and when the participant has sought help and type of reception by the healthcare system, proposed diagnosis and suggested or given treatment
2. Health related quality of life.
3. Symptoms induced by arrhythmias
4. Anxiety and worry
5. Anxiety and depression
After the questionnaires, the participants receive the recording equipment and necessary information about how to use it. The ECG monitoring and instant feedback of the findings on a smartphone are performed by a new patient-handled system, the Coala Heart Monitor. The equipment is used by the participants in daily life. They are instructed to record ECG at symptoms and furthermore encouraged to regularly record ECG morning and night regardless of symptoms for 60 days. The participants are able to see the results of the ECG analysis immediately using their smartphone. The results are also at the same time available for the study investigators. If clinically important arrhythmias are detected, the participant is recommended to consult an appropriate physician. . If necessary, the investigators help with the referral to hospital or physician.

What are the possible benefits and risks of participating?
Possible benefits are that previously undetected clinically significant arrhythmias might be diagnosed, and adequate therapy started. Clarifying that underlying arrhythmias causing palpitations are benign might decrease anxiety and stress caused by the palpitation. A possible risk of participation might be that recording ECG regularly and receiving instant diagnoses might increase already present anxiety regarding palpitations.

Where is the study run from?
Karolinska Institutet for med and Karolinska University Hospital (Sweden)

When is the study starting and how long is it expected to run for?
February 2018 to November 2018

Who is funding the study?
Karolinska Institutet (Sweden)

Who is the main contact?
Mrs Carina Carnlöf
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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Study information

Scientific Title
ECG-registration in women with palpitations with rapid response by Coala Heart Monitor – effect on symptoms and quality of life and information on frequency of dangerous heart rhythms

Acronym
Red Heart Study

Study objectives
1. To what extent will heart palpitations induce anxiety, worries and reduce quality of life?
2. To what extent will a patient-managed ECG monitoring system document underlying heart rhythms when having paroxysmal palpitations?
3. Is there a correlation between the prevalence of arrhythmias and mental symptoms and quality of life?
4. If getting instant feedback on the ECG rhythm, will that decrease mental symptoms and/or increase quality of life?

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approved 09/04/2018, Regional Institutional Ethics Committee (Etikprövningsmyndigheten, Box 2110, 750 02 Uppsala. Telephone: +46 (0)10-745 08 00. Email: registrator@etikprovning.se), Dnr: 4-84/2018

Study design
Prospective observational study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Home

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Palpitations

Interventions
After informed consent, the participants borrowed the heart monitor (Coala Heart Monitor) and were instructed via the internet on how to use it and when needed via telephone support. The participants then used the ECG monitor when having palpitations but every morning and evening regardless of symptoms for 60 days. Prior to the study start, demographic data were collected, including, age, place of residence and questions such as; “How often do you experience symptoms?”,” Have you consulted the health service for your symptoms?” , “Did you get any treatment for your symptoms?”, “Did you feel that the health care staff believed and took you seriously when seeking medical care for your symptoms?” The questionnaires answered at baseline and after 60 days ECG monitoring were the RAND -36 to assess health-related quality of life, the Symptoms Checklist: Frequency and Severity (SCL), an instrument specifically designed to assess arrhythmia symptoms, the Generalized Anxiety Disorder (GAD-7) for the assessment of anxiety, and the Hospital Anxiety and Depression Scale (HAD) for assessment of anxiety and depression.

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure
Measured at the beginning of the study and after 2 months of ECG recording:
1. Health-related quality of life assessed using RAND-36

2. Anxiety assessed using Generalized Anxiety Disorder (GAD-7)
3. Anxiety and depression assessed using the Hospital Anxiety and Depression Scale (HAD)
4. Arrhythmia symptoms assessed using Symptoms Checklist: Frequency and Severity (SCL)

Secondary outcome measures
Prevalance of arrhythmia when having heart palpitation measured using ECG recordings during the study period of 2 months

Overall study start date
25/02/2018

Completion date
30/11/2018

Eligibility

Key inclusion criteria
1. Women with symptomatic palpitations
2. Age over 18 years
3. Able to read and write Swedish fluently
4. Have a smartphone or tablet
5. Have a Swedish eAuthentification (BankID)
6. Able to handle a digital approach

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
To detect a 30% change of in mental symptoms after 60 days of ECG registration with rapid feedback of the heart rhythm, it was estimated that 350 individuals were needed to achieve a power of 80% and an alfa of 0.05. To detect a correlation between symptoms and severe arrhythmias with the same conditions, it was estimated that 900 individuals were needed.

Total final enrolment
1020

Key exclusion criteria
Earlier known AF or atrial flutter (AFL)

Date of first enrolment
01/06/2018

Date of final enrolment
15/07/2018

Locations

Countries of recruitment
Sweden

Study participating centre
Karolinska Institutet for med and Karolinska University Hospital
Heart & Vascular Theme
Norbacka S1:02
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Sponsor information

Organisation
Karolinska Institutet

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Sponsor type
University/education

ROR
https://ror.org/04hmgwg30

Funder(s)

Funder type
University/education

Funder Name
Karolinska Institutet

Alternative Name(s)
Karolinska Institute, KI

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Sweden

Results and Publications

Publication and dissemination plan
1. Method
2. Questionnaires
3. Prevalance

Intention to publish date
01/03/2020

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 Per Insulander (per.insulander@ki.se).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			08/11/2019	No	No
Results article	results	18/02/2021	22/02/2021	Yes	No