

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	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 04/11/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 22/02/2021	Condition category Circulatory System	<input type="checkbox"/> 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?

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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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

Study type(s)

Quality of life

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(s)

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)

Key secondary outcome(s)

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

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 eAuthentication (BankID)
6. Able to handle a digital approach

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

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
Stockholm

Sweden
S-17176

Sponsor information

Organisation

Karolinska Institutet

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

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?
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Results article	results	18/02/2021	22/02/2021	Yes	No
Protocol file			08/11/2019	No	No