ISRCTN 37374

Study protocol

Red Heart Study

ECG recording in women with palpitations with rapid response by Coala Heart Monitor – effect on symptoms and quality of life and information on the frequency of clinically significant arrhythmias

Background

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 extras 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), paroxsysmal supraventricular arrhythmias and ventricular arrhythmias. 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 like heart stop causing sudden death.

Recent research has revealed sex-differences in the appearance of rhythm disturbances as well as differences in pathophysiology, symptoms, and treatment. Women with arrhythmias are more often misdiagnosed and undertreated both with invasive treatment and with drug treatment compared with men. Therefore, it is important with documentation of palpitations and their association with rhythm disturbances also among women.

It is often difficult with standard ECG recording technology (so-called Holter registration where the ECG is continuously recorded 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 environment. The possibility to record ECG in connection with symptoms is hereby increased. Furthermore, getting a rapid response on your 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.

Online surveys with web-based self-administered questionnaires have increased in use the last decade. It has proved to be highly acceptable among the patients, to improve the quality of data with low numbers of missing data and with less cost for the patient and the health care system.

However, many clinical studies both in patients and healthy volunteers take longer to finalize than original planned because of the long recruitment periods. The inclusion procedures are usual complicated and time consuming due to all formalities. Furthermore, meeting with the study participants for information and signing the informed consent requires special employees and meeting rooms. Therefore, to speed up the inclusion rate, internet will be used including signing of the informed consent. This study will be completely digital including getting instructions how to use the heart monitor with rapid feed-back on a smartphone and answering of the questionnaires before and after two months.

Objectives

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 arrhythmia 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?

Hypothesises

1. Arrhythmias of clinical importance are rarely causing palpitations.
2. Clarifying underlying heart rhythms in individuals with palpitation decreases anxiety and stress and increases quality of life.

Recruiting participants

The members of the NGO 1.6 million club for Women's Health will be informed about a study concerning heart palpitations and ECG findings via mail or lectures. The same request will be sent out via social media. A short description of the study will be distributed. Women declaring their interest to participate will be contacted for further information including the patient informed consent.

Questionnaires

Before the start of the ECG monitoring (questionnaires 1-5) and at study stop after 2 months (questionnaires 2-5) the participants will be asked to answer the following questionnaires:

1. Questions about age, frequency of symptoms, if and when the participant has consulted the healthcare system due to palpitations, what kind of help did they receive, proposed diagnosis and suggested or given treatment.
2. RAND 36, an international well validated instrument for measuring health related quality of life. Is has previously been used in Sweden for patients with arrhythmias like atrial fibrillation and supraventricular tachycardia.
3. SCL (the Symptoms Checklist: Frequency and Severity), an instrument specifically constructed for evaluating symptoms induced by arrhythmias. The Swedish translation has recently been approved.
4. GAD (Generalized Anxiety Disorder), an international well validated instrument for measuring problems with anxiety and worry.
5. HAD (Hospital Anxiety and Depression Scale), an international well validated instrument for measuring anxiety and depression

ECG-monitoring

After having answered the questionnaires, the participants get the recording equipment and necessary information about how to use it. The ECG monitoring and instant feedback about the ECG findings on a smartphone are performed by a new patient handled system, the Coala Heart Monitor. The system consists of a wireless unit for registration with integrated ECG electrodes for using the recording unit with the help of a smartphone. Furthermore, a cloud-based system of analyses connected to a data platform that can be used by the patient and health care system.

The ECG algorithm detects 10 different types of arrhythmias with a high sensitivity
The equipment will be used by the study-participants in daily life. They will be instructed to record ECG at symptoms and furthermore encouraged to regularly record ECG morning and night regardless of symptoms for 60 days.

When doing a recording, the participant also must mark on their smartphone app if they experience any or no symptom: palpitation, anxiousness, stress, chest pain, dizziness, other specified symptom, or no symptom.

Feedback regarding underlying heart-rhythm

The participants will be able to see the results of the ECG analysis immediately in their smartphone. The results are also at the same time available for the study investigators. If clinically important arrhythmias are detected, the participant will be recommended to consult an appropriate physician. If necessary, the investigators will help with the referral to hospital or physician.

ECG analysis

In a first step, analysis of recorded ECGs is performed by the Coala Heart Monitor system algorithm. In a second step, heart rhythms deviating from normal sinus rhythm are manually interpreted by the investigators. In a third step, analysis the prevalence of recorded arrhythmias is done. In a fourth step, comparison of different symptoms and underlying heart rhythms is done. In a fifth step, correlation between symptoms, recorded arrhythmias and results of the questionnaires is done.

All ECG recordings will be – as all other data – primarily documented digitally, with actual manual interpretation of ECG done online.

Power

To detect a 30% change in mental symptoms after 60 days of ECG recordings with rapid feedback of the heart rhythm, it was estimated that 35o individuals were needed to achieve a power of 80% with an alfa of 0.05. To detect a correlation between symptoms and clinically significant arrhythmias with the same conditions, it was estimated that 900 individuals were needed.

References

1. Andersson S, et al. Twenty-four-hour electrocardiography in a healthy elderly population. Gerontology 1988;34:139-44.
2. Kirshhof P, et al. 2016 ESC Guidelines for the management of atrial fibrillation developed in collaboration with EACTS. European Heart J 2016;38:2893-962.
3. Orejareno LA, et al. Paroxysmal supraventricular tachycardia in the general population. J Am Coll Cardiol. 1998;31:150-7.
4. Granada J, et. Incidence and predictors of atrial flutter in the general population. J Am Coll Cariol. 2000;36:2242-6.
5. Dagres N, et al. Gender related differences in presentation, treatment, and outcome of patients with atrial fibrillation in Europe. J Am Coll Cardiol. 2007;49:572-7.
6. Carnlöf C, et al. Women with PSVT are often misdiagnosed, referred later than men, and have more symptoms after ablation. Scand Cardiovasc J. 2017;51:299-307.
7. Svennberg, et al. Safe automatic one-lead electrocardiogram analysis in screening for atrial fibrillation. Europace 2016:10.1093/europace/euw286.
8. Olsson A, Samuelsson M. Abstract 12893: Symptom-Ruled Real World Arrhythmic Recordings With an Internet Based System. Circulation. 2018;138.