Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Nov 2026

Assessment of the function of the telemedicine device in order to report lead 2 of electrocardiogram, heart rate, body temperature, peripheral pulse rate and the level of blood oxygen

Protocol summary

Study aim
Assessment of the function of the telemedicine device in order to report lead 2 of electrocardiogram, heart rate, body temperature, peripheral pulse rate and the level of blood oxygen

Design
Two arm parallel group unblinded, non-randomised, phase 3 trial on 60 patients with cardiac arrhythmia and 20 adults without cardiac arrhythmia

Settings and conduct
This study will be conducted in the Cardiology Clinic of Babol University of Medical Sciences. Adults who refer for check-up or cardiological treatment will be assessed without any blinding in two intervention and control groups. The intervention group includes the patients who have at least one of the 6 types of common cardiac arrhythmias (including AF, VT, PSVT, PVC, PAC, or AT) and the telemedicine device is installed on their body. The control group includes people who do not have any of the 6 common types of cardiac arrhythmia and the telemedicine device is installed on their body. Allocation of the participants to two intervention and control groups will be carried-out without randomization.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 18 years and over; Refer to the cardiology clinic for check-up or cardiological treatment
Exclusion criteria: The patient's inability to use the telemedicine device; Not to provide consent to participate in the study

Intervention groups
Intervention group: Patients who have at least one of the 6 common types of cardiac arrhythmias diagnosed by the cardiologist and the telemedicine device will be installed on their body. Control group: People who do not have any of the 6 common types of cardiac arrhythmia and the the telemedicine device will be installed on their body.

Main outcome variables
Lead 2 of the electrocardiogram; Heart rate; Body temperature; Peripheral pulse rate; The level of blood oxygen

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20230808059080N1**
Registration date: **2023-08-14, 1402/05/23**
Registration timing: **registered_while_recruiting**

Last update: **2023-08-14, 1402/05/23**
Update count: **0**

Registration date
2023-08-14, 1402/05/23

Registrant information
Name
Mohammad Taghi Hedayati
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-08-12, 1402/05/21
Expected recruitment end date
2023-09-22, 1402/06/31
Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of the function of the telemedicine device in order to report lead 2 of electrocardiogram, heart rate, body temperature, peripheral pulse rate and the level of blood oxygen

Public title

Assessment of the function of the telemedicine device

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 years and over Refer to the cardiology clinic for check-up or cardiological treatment

Exclusion criteria:

The patient´s inability to use the telemedicine device Not to provide consent to participate in the study by the patient

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **80**

More than 1 sample in each individual

Number of samples in each individual: **12**

In each participant, three times of measurement with 5-minute intervals using 3 SEMS-HIOT devices and one standard device

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Babol University of Medical Sciences

Street address

Babol University of Medical Sciences, Ganjafrooz Avenue, Babol

City

Babol

Province

Mazandaran

Postal code

4717647754

Approval date

2023-03-06, 1401/12/15

Ethics committee reference number

IR.MUBABOL.REC.1401.180

Health conditions studied

1

Description of health condition studied

Atrial fibrillation and atrial flutter (AF)

ICD-10 code

I48.9

ICD-10 code description

Unspecified atrial fibrillation and atrial flutter

2

Description of health condition studied

Ventricular tachycardia (VT)

ICD-10 code

I47.2

ICD-10 code description

Ventricular tachycardia

3

Description of health condition studied

Paroxysmal supraventricular tachycardia (PSVT)

ICD-10 code

I47.1

ICD-10 code description

Supraventricular tachycardia (paroxysmal)

4

Description of health condition studied

Premature ventricular contractions (PVC)

ICD-10 code

I49.3

ICD-10 code description

Ventricular premature depolarization

5

Description of health condition studied

Premature atrial contractions (PAC)

ICD-10 code

I49.1

ICD-10 code description

Atrial premature depolarization

6

Description of health condition studied
Atrial tachycardia (AT)
ICD-10 code
I47.1
ICD-10 code description
Supraventricular tachycardia

Primary outcomes

1

Description
Lead 2 of the electrocardiogram
Timepoint
Minute 1, minute 6 and minute 11
Method of measurement
Patient lying supine on a medical bed, after 15 minutes of rest, the medical care device (including three chest leads, an axillary thermometer and a wireless finger pulse oximeter) is installed on his body. The participant will rest again for 5 minutes and then the research primary variables will be measured. Data recording will be initiated at minute 1. With 5-minute intervals, three times of measurement will be carried out on each patient using three SEMS-HIOT devices produced by the Behbood Samane Hooshmand Teb Company affiliated to Technology Incubator of Babol University of Medical Sciences, and one time measurement with a standard device.

2

Description
Body temperature
Timepoint
Minute 1, minute 6 and minute 11
Method of measurement
Patient lying supine on a medical bed, after 15 minutes of rest, the medical care device (including three chest leads, an axillary thermometer and a wireless finger pulse oximeter) is installed on his body. The participant will rest again for 5 minutes and then the research primary variables will be measured. Data recording will be initiated at minute 1. With 5-minute intervals, three times of measurement will be carried out on each patient using three SEMS-HIOT devices produced by the Behbood Samane Hooshmand Teb Company affiliated to Technology Incubator of Babol University of Medical Sciences, and one time measurement with a standard device.

3

Description
The level of blood oxygen
Timepoint
Minute 1, minute 6 and minute 11
Method of measurement
Patient lying supine on a medical bed, after 15 minutes of rest, the medical care device (including three chest leads, an axillary thermometer and a wireless finger pulse oximeter) is installed on his body. The participant will rest again for 5 minutes and then the research primary variables will be measured. Data recording will be initiated at minute 1. With 5-minute intervals, three times of measurement will be carried out on each patient using three SEMS-HIOT devices produced by the Behbood Samane Hooshmand Teb Company affiliated to Technology Incubator of Babol University of Medical Sciences, and one time measurement with a standard device.

4

Description
Peripheral pulse rate
Timepoint
Minute 1, minute 6 and minute 11
Method of measurement
Patient lying supine on a medical bed, after 15 minutes of rest, the medical care device (including three chest leads, an axillary thermometer and a wireless finger pulse oximeter) is installed on his body. The participant will rest again for 5 minutes and then the research primary variables will be measured. Data recording will be initiated at minute 1. With 5-minute intervals, three times of measurement will be carried out on each patient using three SEMS-HIOT devices produced by the Behbood Samane Hooshmand Teb Company affiliated to Technology Incubator of Babol University of Medical Sciences, and one time measurement with a standard device.

5

Description
Heart rate
Timepoint
Minute 1, minute 6 and minute 11
Method of measurement
Patient lying supine on a medical bed, after 15 minutes of rest, the medical care device (including three chest leads, an axillary thermometer and a wireless finger pulse oximeter) is installed on his body. The participant will rest again for 5 minutes and then the research primary variables will be measured. Data recording will be initiated at minute 1. With 5-minute intervals, three times of measurement will be carried out on each patient using three SEMS-HIOT devices produced by the Behbood Samane Hooshmand Teb Company affiliated to Technology Incubator of Babol University of Medical Sciences, and one time measurement with a standard device.

Secondary outcomes

1

Description
Acceptance of the device by the patient
Timepoint
At the end of the intervention
Method of measurement

By asking a question about the patient's satisfaction with the device

Intervention groups

1

Description
Intervention group: The patients who have at least one of the 6 types of common cardiac arrhythmias diagnosed by the cardiologist and the telemedicine device manufactured in Behbood Samane Hooshmand Teb Company affiliated to Technology Incubator of Babol University of Medical Sciences is installed on their body. This device consists of three chest leads, a thermometer in the armpit and a wireless pulse oximeter that is placed on the participant's finger.
Category
Diagnosis

2

Description
Control group: The adults who do not have any of the 6 types of common cardiac arrhythmias and the telemedicine device manufactured in Behbood Samane Hooshmand Teb Company is installed on their body. This device consists of three chest leads, a thermometer in the armpit and a wireless pulse oximeter that is placed on the participant's finger.
Category
Diagnosis

Recruitment centers

1

Recruitment center
Name of recruitment center
Cardiology Clinic of Babol University of Medical Sciences
Full name of responsible person
Fazel Tarkhan
Street address
Babol University of Medical Sciences, Ganjafrooz Avenue, Babol
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Mehdi Rajabnia
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Mazandaran
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Phone
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Email
research@mubabol.ac.ir
Web page address
https://research.mubabol.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Babol University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Fazel Tarkhan
Position
Physician and inventor
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Data of this study can be shared after de-identifying the individuals.

When the data will become available and for how long
The access period starts 3 months after the results are published.

To whom data/document is available
Data related to this study will be available both to researchers working in academic and scientific centers and to people working in industry.

Under which criteria data/document could be used
After sending the request email to the corresponding author, data related to this study will be available both to researchers working in academic and scientific centers and to people working in industry.

From where data/document is obtainable
The corresponding author with email address mt.hedayati@mubabol.ac.ir

What processes are involved for a request to access data/document
The data related to this study will be available in time up to two months after sending the request email to the corresponding author.

Comments