

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

A comparative study of clinical parameters of produced temporary cardiac pacemaker with temporary cardiac pacemaker model ev4543

Protocol summary

Kermanshah University of Medical Sciences

Summary

In this study, thirty patients who are admitted to Emam Ali hospital and they need pacemaker with any reasons are studied. In this study, We compare important parameters of both of pacemakers that are rate, sense and out put. Actually temporary pacemaker model ev4543 is set as reference and standard device and clinical parameters of this device compare with clinical parameters of produced pacemaker.

Expected recruitment start date

2012-12-05, 1391/09/15

Expected recruitment end date

2013-08-22, 1392/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013062113730N1**

Registration date: **2013-08-13, 1392/05/22**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-08-13, 1392/05/22

Registrant information

Name

Yousef Darabi Moghadam

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1821 3077

Email address

y.darabi@tickums.org

Recruitment status

Recruitment complete

Funding source

vice-chancellery of research & technology affairs,

Scientific title

A comparative study of clinical parameters of produced temporary cardiac pacemaker with temporary cardiac pacemaker model ev4543

Public title

A comparative study of clinical parameters of produced temporary cardiac pacemaker with temporary cardiac pacemaker model ev4543

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: patients who are candidate for open heart surgery (CABG) and have age between 50-90 years old. Exclusion criteria: tachycardia and unstable cardiac health condition,

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kermanshah University of Medical Sciences

Street address

Building no 2, Shahid Beheshti Boulevard,
Kermanshah University of Medical Sciences

City

Kermanshah

Postal code

Approval date

2012-12-04, 1391/09/14

Ethics committee reference number

/7/420/4608/پ

Health conditions studied

1

Description of health condition studied

Dependence on temporary pacemaker

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

sensitivity threshold

Timepoint

15 minets for any device

Method of measurement

observation variables on device

2

Description

Rate

Timepoint

15 minets for any device

Method of measurement

observation variables on patient monitoring system and device

3

Description

out put threshold

Timepoint

15 minets for any device

Method of measurement

observation variables on patient monitoring system and device

Secondary outcomes

empty

Intervention groups

1

Description

Clinical parameters of temporary pacemaker model EV4543 that include rate, sense, out put compare with clinical parameters of produced pacemaker on patient dependence on temporary pacemaker.(self-control patient study)

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Ali Cardiovascular Center

Full name of responsible person

Street address

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice - Chancellery of Research & Technology Affairs
Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Farid Najafi

Street address

Building no 2, Shahid Beheshti Boulevard,
Kermanshah University of Medical Sciences

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Kermanshah

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice - Chancellery of Research & Technology Affairs
Kermanshah University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Yousef Darabimoghadam

Position

Bachelor of biomedical engineering

Other areas of specialty/work**Street address**

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty

Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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