# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## Comparison of left ventricle segments contraction pattern by echocardiography in Right ventricular apical pacing with Right ventricular septal pacing in patient with complete heart block in Tabriz Shahid Madani hospital.

## Protocol summary


**Summary**

Objectives: The aim of this study is comparsion of new pacemaker implantation method with traditional method. Design: This study is a randomised clinical trial with control group. Setting and condct: Sixty patients with symptomatic bradycardia and left ventricular ejection fraction more than 50% which candidates for permanent pacemaker placement will be enrolled the survey. Patients will be divided into two groups randomly which pacemaker lead will be implanted at right ventricle apex in one group and for another group it will be implanted in septum. All patients will be studied six months later by echocardiography and the results of these two groups will be compared. Participants including major eligibility criteria: The major inclusion criteria is patients with symptomatic bradycardia and complete heart block with left ventricular ejection fraction more than 50% that candidate for permanent pacemaker and the major exclusion criteria will be consist of symptomatic coronary artery disease; Apparent valvular heart disease; Cardiomyopathy and left venticular ejection fraction less than 50% before pacemaker implantation. Intervention: Eligible patients will be divided into two groups randomly which pacemaker lead will be implanted at right ventricle apex in one group and for another group it will be implanted in septum. Main outcome: The primery outcome is evaluation of left ventricle segments contraction pattern in new method in comparsion of traditional pacemaker implantation method that will be done by echocardiography 6 month after pacemaker implantation.


## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2014012216314N1**
Registration date: **2014-07-03, 1393/04/12**
Registration timing: **prospective**

Last update:
Update count: **0**

**Registration date**

2014-07-03, 1393/04/12

**Registrant information**

**Name**

Kamran Mohammadi

**Name of organization / entity**

Tabriz Medical University

**Country**

Iran (Islamic Republic of)

**Phone**

+98 41 1380 6072

**Email address**

mohammadik@tbzmed.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

Vice chancellor for research, Tabriz University of Medical Sciences.

**Expected recruitment start date**

2014-07-06, 1393/04/15

**Expected recruitment end date**

2015-06-22, 1394/04/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**
Comparison of left ventricle segments contraction pattern by echocardiography in Right ventricular apical pacing with Right ventricular septal pacing in patient with complete heart block in Tabriz Shahid Madani hospital.

**Public title**
Comparsion of results between traditional and new pacemaker implantation methods.

**Purpose**
Treatment

**Inclusion/Exclusion criteria**
Inclusion criteria: Patients with symptomatic bradycardia and complete heart block with left ventricular ejection fraction that candidate for permanent pacemaker.
Exclusion criteria: Symptomatic coronary artery disease; Apparent valvular heart disease; Cardiomyopathy; Left ventricular ejection fraction less than 50% before pacemaker implantation.

**Age**
No age limit

**Gender**
Both

**Phase**
2-3

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **60**

**Randomization (investigator's opinion)**
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**
Tabriz Medical University ethic committee

**Street address**
Number 14, Ethic committee, Tabriz Medical University Central building, Golgasht street, Azadi street, Tabriz.

**City**
Tabriz

**Postal code**

**Approval date**
2013-09-23, 1392/07/01

**Ethics committee reference number**
92153

## Health conditions studied

### 1

**Description of health condition studied**
Complete atrioventricular block

**ICD-10 code**
I44.2

**ICD-10 code description**
Complete heart block NOSThird-degree block

## Primary outcomes

### 1

**Description**
Amount of different segments contraction of LV

**Timepoint**
6 month after intervention

**Method of measurement**
With speckle tracking echocardiography

## Secondary outcomes

### 1

**Description**
Left ventricle ejection fraction

**Timepoint**
6 month after pace maker implantation

**Method of measurement**
With echocardiography

## Intervention groups

### 1

**Description**
Control group: In the control group pacemaker will be implanted subcutaneously by a 10cm section in the left hemi thorax. In this group the Pacemaker leads will be implanted in right ventricular apex.

**Category**
Treatment - Surgery

### 2

**Description**
Intervention Group: In the interventional group pacemaker will be implanted subcutaneously by a 10cm section in the left hemi thorax. In this group the Pacemaker leads will be implanted in right ventricular septum.

**Category**
Treatment - Surgery

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Tabriz Shahid Madani hospital

**Full name of responsible person**
Kamran Mohammadi resident of cardiology

**Street address**
Number 12, Shahid Madani hospital, Daneshgah street, Tabriz

**City**
Tabriz

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Vice chancellor for research, Tabriz University of Medical Sciences.

**Full name of responsible person**
Research committee assistant, Dr Shahsar.

**Street address**
Number 14, Tabriz Medical University Central building, Golgasht street, Azadi Street, Tabriz.

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**Grant name**

**Grant code / Reference number**

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

**Title of funding source**
Vice chancellor for research, Tabriz 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**
Tabriz Medical University

**Full name of responsible person**
Kamran Mohammadi

**Position**
Rezidence of cardiology

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

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Hasan Javadzadeghan

**Position**
Assistant professor of cardiology

**Other areas of specialty/work**

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## Person responsible for updating data

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Tabriz Medical University

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Kamran Mohammadi

**Position**
Resident of cardiology

**Other areas of specialty/work**

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## 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*