Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison effect of three chamber pacemaker in patients with systolic dysfunction, on sign and symptom when its programmed based on echo cardiography versus factory suggested

Protocol summary

Summary

Cardiac resynchronization therapy is beneficial for a majority of patients with medically refractory heart failure due to severe LV systolic dysfunction and prolonged interventricular conduction to optimally programmed Atrioventricular delay during CRT can be also important to maximize the response in left ventricular function.several echocardiographic method have been reported to be useful for determination of the optimal AVD .In this trial 40 patient with left ventricular systolic dysfunction, will be randomized in a fixed AV delay(factory suggested)and AV delay determined by echocardiography(inclusion criteria:patient with systolic left ventricular dysfunction; Ejection fraction<35%; sinus rhythm;function class 3or4 with medical therapy; QRS duration>120ms).patient will be evaluated by echocardiography and clinical status prior to initiation of CRT and 2 month post implant.we want to comparison function class of patient (primary out come measure)between two group of them.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201102232474N3**
Registration date: **2011-09-28, 1390/07/06**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-09-28, 1390/07/06

Registrant information

Name

Mehdi Toluey Khormazard

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1668 6560

Email address

drmtoluey@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research Tabriz university of medical sciences

Expected recruitment start date

2010-03-20, 1388/12/29

Expected recruitment end date

2011-09-21, 1390/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison effect of three chamber pacemaker in patients with systolic dysfunction, on sign and symptom when its programmed based on echo cardiography versus factory suggested

Public title

Comparison of programmed parameters of three chamber pacemaker based on echocardiographic finding versus factory suggested parameters

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria:patient with systolic left ventricular

dysfunction; Ejection fraction<35%; sinus rhythm;function class 3or4 with medical therapy; QRS duration>120ms. exclusion criteria:severe structural valvular disease;Intra cardiac shunt

Age
No age limit

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **40**

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
Ethics committee of Tabriz University of Medical Sciences

Street address
Tabriz University of Medical Sciences, Golgasht street, Azadi street, Tabriz

City
Tabriz

Postal code

Approval date
2010-08-20, 1389/05/29

Ethics committee reference number
5.4.9588

Health conditions studied

1

Description of health condition studied
Left Ventricular Systolic Dysfunction

ICD-10 code
I42.0

ICD-10 code description
Dilated Cardiomyopathy

Primary outcomes

1

Description
Function Class

Timepoint
Befor intervention and two month after intervention

Method of measurement
6min walk

Secondary outcomes

1

Description
Left Ventricular Function

Timepoint
Befor intervention and two month after intervention

Method of measurement
Echocardiography

Intervention groups

1

Description
Intervention:After implantation of three chamber pace maker " device is programmed on echo cardiography guided and patient should be followed after 2 month.

Category
Treatment - Devices

2

Description
Control:in this group after implantation of pace maker , device is programmed on factory consults and patient followed after 2 month.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Madany Heart Center

Full name of responsible person
Dr Ali Abbasnejad

Street address
Madani hospital, Golgasht st, Azadi st

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
Dr Rasool Azarfarin
Street address
Tabriz University of Medical Scienc, Golgasht street, Azadi street, Tabriz
City
Tabriz
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 University of Medical Sciences
Full name of responsible person
Dr Fariborz Akbarzadeh
Position
Professor
Other areas of specialty/work
Street address
Shahid Madani Hospital, Golgasht street, Azadi street, Tabriz
City
Tabriz
Postal code
Phone
+98 914 114 2328
Fax
Email
F_AKBARZADEH@Yahoo.Com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr Fariborz Akbarzadeh
Position
Professor
Other areas of specialty/work
Street address
Shahid Madani Hospital, Golgasht street , Azadi Street, Tabriz
City
Tabriz
Postal code
Phone
+98 914 114 2328
Fax
Email
F_AKBARZADEH@Yahoo.Com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Tabriz University of medical Sciences
Full name of responsible person
Ali Abbasnejad
Position
Cardiology Assistant
Other areas of specialty/work
Street address
Tabriz University, Golgasht street, Azadi street, Tabriz
City
Tabriz
Postal code
Phone
Fax
Email
dr.abbasnezhad@yahoo.com
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