

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 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

Before intervention and two months after intervention

Method of measurement

6min walk

Secondary outcomes

1

Description

Left Ventricular Function

Timepoint

Before intervention and two months 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 months.

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 months.

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