Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluation of contractile reserve by Milrinone as a predictor of response to Cardiac Resynchronization Therapy in patients with heart failure.

Protocol summary

Summary

Our aim of this study is to evaluate of left ventricular contractile reserve by stress echocardiography with milrinone in patients with advanced heart failure who have candidated for a treatment named Cardiac Resynchronization Therapy (CRT), an implantable device.30 subjects with advanced heart failure who have left ventricular ejection fraction equivalent or less than 35%, Left bundle branch block with sinus rhythm, wideness of QRS more than 120msec, NIHA (New York Heart Association) functional class 3 & 4 and poor response to medical therapy (Inclusion criteria), will select and undergo Milrinone Stress Echocardiography for evaluate left ventricular contractile reserve before device implantation and 4 to 6 months later by routine echocardiography. Comparison response to Milrinone with response to device , will reveal predictor rule of Milrinone drug. Primary outcome is improvement left ventricular contractility according to echocardiographic values specially left ventricular ejection fraction, end diastolic volume, and end systolic volume. Other out comes include functional capacity on base of history and 6 minutes walk distance and finally frequency of hospitalization.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201201238808N1**
Registration date: **2012-03-18, 1390/12/28**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-03-18, 1390/12/28

Registrant information

Name
Karim Mohammadi Kheyrabadi
Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Science

Expected recruitment start date

2011-09-23, 1390/07/01

Expected recruitment end date

2012-03-20, 1391/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of contractile reserve by Milrinone as a predictor of response to Cardiac Resynchronization Therapy in patients with heart failure.

Public title

Prediction of CRT implantation benefit with Milrinone stress echocardiography

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria: Heart failure patients who have LBBB with sinus rhythm, QRS>120msec, LVEF<35%, NIHA function class 3 & 4 and poor response to medical

therapy. Exclusion criteria: Hypersensitivity to Milrinone,AF rhythm,severe COPD, hypertrophic and restrictive cardiomyopathies, acute myocarditis, correctable valvular diseases and acute coronary syndrome.

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)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tabriz University of Medical Science

Street address
Daneshgah street, Tabriz

City
Tabriz

Postal code

Approval date
2011-05-30, 1390/03/09

Ethics committee reference number
1949/4/5

Health conditions studied

1

Description of health condition studied
Heart Failure

ICD-10 code
I50

ICD-10 code description
Heart failure

Primary outcomes

1

Description
Echocardiographic Values of left ventricular contractility

Timepoint
Admission time(basic & with Milrinon),4- 6 months afterCRT implantation

Method of measurement
Echocardiography

Secondary outcomes

1

Description
NIHA function class ,frequency of hospitalization

Timepoint
Before & 4- 6 months after intervention

Method of measurement
6 minute walking test, history

Intervention groups

1

Description
Before CRT implantation and after performing basic echocardiography, drug administrating (Milrinone) with loading dose 50 microgram/kg BW in 10 miuntes and continuing 5 microgram/kg/minute for 10 to15 miuntes intravenously infusion,after repeating echocardiography drug will discotinue

Category
Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center
Tabriz Shahid Madani Hospital

Full name of responsible person
Karim Mohammadi Kheyrabadi

Street address
Daneshgah Street, Tabriz Shahid Madani Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Science

Full name of responsible person
Research Center

Street address

Daneshgah 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

Tabriz University of Medical Science

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

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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