

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 outcomes 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

Tabriz University of Medical Sciences

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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 after CRT 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 minutes and continuing 5 microgram/kg/minute for 10 to 15 minutes intravenously infusion, after repeating echocardiography drug will discontinue

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

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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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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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