

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Evaluation of the effect of iron replacement therapy on symptom and quality of life in patients with chronic heart failure and iron deficiency who referred to Isfahan's Shariarti hospital in 1392-93

Protocol summary

Summary

This is a clinical trial for evaluation of iron replacement therapy on symptoms and quality of life in patients with chronic heart failure and iron deficiency anemia . in this study 46 patients with stable chronic heart failure and iron deficiency who are content to take part in this study and have no hemoglobinopathy , follic acid or vitamin B12 deficiency will be registered in the study and will recieve parental iron. before starting intervention hemoglobin level,serum iron,Total iron binding capacity,transferrin saturation and ferritin will be measured.also patient's quality of life and 6 minute walk test will be evaluated.then iron depletion will be calculated by: $3.2(\text{normal Hemoglobin-patient Hemoglobin}) \times \text{body weight} + 1000$ for males and $3.2(\text{normal Hemoglobin-patient Hemoglobin}) \times \text{body weight} + 500$ for females Having gotten patients consent, they will treated by 200 mg intravenous iron every week and after complete replacement therapy , patients will be reevaluated in terms of hemoglobin level,serum iron,total iron binding capacity,transferrin saturation, ferritin , patient's quality of life and 6 minute walk test. Finally all data will be analyzed by statistical software

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013112813828N5**
Registration date: **2014-03-18, 1392/12/27**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-03-18, 1392/12/27

Registrant information

Name

Ahmad Mirdamadi

Name of organization / entity

Islamic Azad university ,Najafabad branch

Country

Iran (Islamic Republic of)

Phone

+98 31 1223 8028

Email address

drsamirdamadi@pmd.iaun.ac.ir

Recruitment status

Recruitment complete

Funding source

Islamic Azad University,Najafabad branch

Expected recruitment start date

2014-03-11, 1392/12/20

Expected recruitment end date

2014-09-21, 1393/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of iron replacement therapy on symptom and quality of life in patients with chronic heart failure and iron deficiency who referred to Isfahan's Shariarti hospital in 1392-93

Public title

Effect of iron replacement therapy in patients with chronic heart failure and iron deficiency anemia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria:patient's consent;patients with stable chronic heart failure;Iron deficiency anemia;Age between 30 and 75 years old exclusion criteria:No consent to participate in study;patient with unstable heart failure;Patient with hemoglobinopathy;Patient with B12 and follic acid deficiency;Pregnancy;Age less than30 or more than75 years old

Age

From **30 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **46**

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**

Isfahan University Of Medical Sciences

Street address

azadi square

City

isfahan

Postal code**Approval date**

2014-02-06, 1392/11/17

Ethics committee reference number

492038

Health conditions studied**1****Description of health condition studied**

chronic heart failure

ICD-10 code

I50

ICD-10 code description

Heart failure

Primary outcomes**1****Description**

6 Minute Walk Test

Timepoint

Before intervention and also afte iron deficiency anemia treatment

Method of measurement

This test measures the distance that a patient can quickly walk on a flat, hard surface in a period of 6 minutes

2**Description**

Quality Of Llife

Timepoint

Before intervention and also after iron deficiency anemia treatment

Method of measurement

Quality Of Llife Questionnaire

3**Description**

New York Heart Association Functional Classification

Timepoint

Before intervention and also afte iron deficiency anemia treatment

Method of measurement

patient's words

Secondary outcomes**1****Description**

serum creatinine

Timepoint

before intervention and after iron deficiency anemia treatment

Method of measurement

jaffe

2**Description**

Glomerular filtration rate

Timepoint

before intervention and after iron deficiency anemia treatment

Method of measurement

$(140 - \text{age}) * \text{mass}(\text{in kilogram}) * (0.85 \text{ if female} / 72 * \text{serum creatinine}(\text{in mg/dl}))$

Intervention groups**1****Description**

Before starting intervention hemoglobin level,serum iron,Toral iron binding capacity,transferrin saturation and ferritin will be measured.also patient's quality of life and 6 minute walk test will be measured.then iron depletion will be calculated then patients will be received 200 mg intravenous iron every week and after iron replacement therapy, patients will be reevaluated in terms of hemoglobin level,serum iron,total iron binding capacity,transferrin saturation. ferritin , patient's quality of life and 6 minute walk test.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Isfahan Doctor Shariat iHospital

Full name of responsible person

Dr Mirdamadi

Street address**City**

Isfahan

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

Islamic Azad University, Najafabad Branch

Full name of responsible person

Dr.Mirdamadi

Street address

Najafabad, Isfahan

City

Najafabad

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Islamic Azad University, Najafabad Branch

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****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Islamic Azad University, Najafabad Branch

Full name of responsible person

Dr.Mirdamadi

Position

Cardiologist,Fellowship of Echocardiography/Assistant professor of medical school

Other areas of specialty/work**Street address**

Sheikhbahaei Street, Isfahan Hospital,

City

Isfahan

Postal code**Phone**

+98 31 1233 0015

Fax

+98 31 1223 8028

Email

drsamirdamadi@yahoo.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Islamic Azad University, Najafabad Branch

Full name of responsible person

Dr.Mirdamadi

Position

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City

Isfahan

Postal code**Phone**

+98 31 1233 0015

Fax

+98 22 38028

Email

drsamirdamadi@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