Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparating the effect of combination and single therapy of exjade and desferal on ferritin level in patients with major thalassemia

Protocol summary

Summary

The present study aims to compare the effect of combinatory and single therapies of exjade and desferal on ferritin level among patients with major thalassemia. It is a single blind clinic study. 90 patients with major thalassemia attending Mohammad Kermanshahi hospital, under treatment with Deferoxamine hypodermic injection and ferritin level 1000 to 3000 were chosen and randomly divided into three groups each including 30 individuals. The first group received the normal treatment including 40 mg/kg deferoxamine hypodermic daily, 6 days a week. The second group received exjade pills 20 mg/kg daily. The third group was treated with daily injection of 40 mg/kg of deferoxamine hypodermic 3 days a week; exjade pill 10mg/kg was taken simultaneously in the third group. Starfa was used to measure ferritin serum at the beginning of the study and every 3 month during 6 months. Inclusion: being younger than 18; having thalasemia major based on observing clinical symptoms and hemoglobin electrophoresis history; being treated by deferoxamine hypodermic injection and ferritin level 1000 to 3000. Exclusion: inability to digest exjade; hepatitis virologic; LFT; active hepatitis; noncompliance with previous treatment regimens; ALT and AST normal up to 3 times

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015042114333N32**
Registration date: **2015-06-04, 1394/03/14**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-06-04, 1394/03/14

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences

Expected recruitment start date

2015-05-31, 1394/03/10

Expected recruitment end date

2016-01-30, 1394/11/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparating the effect of combination and single therapy of exjade and desferal on ferritin level in patients with major thalassemia

Public title

The effect of therapy of exjade and desferal on ferritin level in patients with major thalassemia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion: being younger than 18; having thalasemia major based on observing clinical symptoms and hemoglobin electrophoresis history; being treated by

deferoxamine hypodermic injection and ferritin level 1000 to 3000. Exclusion:inability to digest exjade; hepatitis virologic; LFT; active hepatitis; noncompliance with previous treatment regimens; ALT and AST normal up to 3 times

Age

To **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **90**

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

Kermanshah University of Medical Sciences

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City

Kermanshah

Postal code

Approval date

2014-06-03, 1393/03/13

Ethics committee reference number

420/7/9591/پ

Health conditions studied

1

Description of health condition studied

Major Thalassemia

ICD-10 code

D56.1

ICD-10 code description

Beta thalassaemia

Primary outcomes

1

Description

Ferritin serum amount

Timepoint

at the beginning of the study and every 3 month for 6 months

Method of measurement

Using starfax device

Secondary outcomes

empty

Intervention groups

1

Description

The second group received exjade pills 20 mg/kg daily. Starfax device was used to measure ferritin serum at the beginning of the study and every 3 month during a 6-month period.

Category

Treatment - Drugs

2

Description

The first group received the normal treatment including 40 mg/kg deferoxamine hypodermic daily for 6 days a week. Starfax device was used to measure ferritin serum at the beginning of the study and every 3 month for 6 months.

Category

Treatment - Drugs

3

Description

The third group was treated with daily injection of 40 mg/kg of deferoxamine hypodermic 3 days a week and exjade pill 10mg/kg was taken simultaneously. Starfax device was used to measure ferritin serum at the beginning of the study and every 3 month during a 6-month period.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mohammad Kermanshahi Hospital

Full name of responsible person

Dr. Shadab Nazari

Street address

Mohammad Kermanshahi Hospital, Crossroads of

Shirkhorshid

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshahu University of Medical Sciences

Full name of responsible person

Koroush Hamzehee

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City

Kermanshah

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kermanshahu 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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Mohammadreza Golpayegani

Position

Professor of Pediatric Hematology and Oncology

Other areas of specialty/work

Street address

Emamreza Hospital, Parastar Boulevard

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Fax

Email

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Web page address

Person responsible for updating data

Contact

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