Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparative study of the efficacy of combination and single therapy of exjade and desferal on ferritin level in patients with major thalassemia

Protocol summary

Summary

Objectives: To compare the effect of the combination and single use of exjade and desferal on ferritin levels in patients with thalassemia major. Design: This study is a clinical trial and has been carried out on patients with thalassemia major that treated with transfusion and regular subcutaneous injection Deferoxamine . Setting and conduct: patients are randomly divided into three groups, prescription drugs are given to each group and Serum ferritin will be measured before and after taking the drug, every 3 months up to 6 months. Participants: Patients with thalassemia major with hemoglobin electrophoresis test, prove to be ill and referred to Kermanshah thalassemia center and regularly treated with transfusion and subcutaneous injection by Deferoxamine. Interventions: the first group (control group) received a dose of 40 mg daily routine Deferoxamine per Kg of body weight subcutaneously, in the second group (Intervention group 1) therapy at a dose of 20 mg tablets exjade per kg in three divided doses with food and in the third group (Intervention group 2) received a dose of 40 mg daily routine Deferoxamine per Kg of body weight 3 days a week and Simultaneously receives exjade oral doses of 10 mg per kg 6 days a week. The main outcome variables: the amount of ferritin before the start of intervention, every 3 months to 6 months after taking the drug.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201412097677N3**
Registration date: **2015-06-07, 1394/03/17**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-06-07, 1394/03/17

Registrant information

Name
Mohamadreza Golpayegani
Name of organization / entity
Kermanshah University of Medical Sciences
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Iran (Islamic Republic of)
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Email address
golpayegani@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kermanshah University of Medical Sciences

Expected recruitment start date

2014-05-22, 1393/03/01

Expected recruitment end date

2015-11-21, 1394/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of the efficacy of combination and single therapy of exjade and desferal on ferritin level in patients with major thalassemia

Public title

Effect of exjade on level in patients with thalassemia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Approved based on clinical symptoms and history of thalassemia and hemoglobin electrophoresis; full cooperation during the study; treatment with deferoxamine subcutaneous injection and ferritin levels below 3000. Exclusion criteria: Deferiprone gastrointestinal intolerance; leukocytes less than 3,000; severe liver disease; ascites; lack of consent, lack of cooperation in the history of previous treatment regimens (blood transfusion and deferoxamine).

Age
To **14 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)
Not 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 Ethics Committee

Street address
Kermanshah University of Medical Sciences- Shahid Beheshti Bolvar- Kermanshah

City
Kermanshah

Postal code

Approval date
2014-06-03, 1393/03/13

Ethics committee reference number
9591

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
Serum ferritin level

Timepoint
Before the intervention; three months after the intervention and six months after intervention

Method of measurement
Based on the results of test ferritin

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group1: Exjade; Novartis plant in France; tablets 20 mg per kg body weight; 3 times a day for 6 months

Category
Treatment - Drugs

2

Description
Intervention group2: Deferoxamine and Exjade; Novartis plant in France; Deferoxamine subcutaneous 40 mg per kg of body weight and tablet Exjade dose of 10 mg per kg of body weight; Deferoxamine once a two days and tablet Exjade once a day for 6 month

Category
Treatment - Drugs

3

Description
Control group:Deferoxamine; Novartis plant in France; subcutaneous 40 mg per kg body weight; once daily for 6 months

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Mohammad Kermanshahi Hospital

Full name of responsible person
Mohammad Reza Golpayegani

Street address
Department of Pediatric, Mohammad Kermanshahi

Hospital, HelalAhmar, Kermanshah

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kermanshah University of Medical Sciences

Full name of responsible person

Farid Najafi

Street address

Vice chancellor for research, Building No. 2 of Kermanshah University of Medical Sciences, Shahidbeheshti Bolvar

City

Kermanshah

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, Kermanshah 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

Kermanshah university of medical sciences

Full name of responsible person

Reza Akramipour

Position

Chief of Department of Pediatrics

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Mohammadreza Golpayegani

Position

oncology of Children

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Shadab Nazari

Position

Resident of Pediatric

Other areas of specialty/work

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Phone

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Fax

Email

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