Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Jun 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
Country
Iran (Islamic Republic of)
Phone
+98 83 1427 6331
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
Street address
Mohammad Kemanshahi Hospital, Helal Ahmar Ave
City
Kermanshah
Postal code
Phone
+98 83 3721 8202
Fax
Email
Akramipur20@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Mohammadreza Golpayegani
Position
oncology of Children
Other areas of specialty/work
Street address
Mohammad Kemanshahi Hospital, Helal Ahmar Ave
City
Kermanshah
Postal code
Phone
+98 83 3721 8202
Fax
Email
golpayegani@kums.ac.ir, mrgolpayegani@yahoo.com
Web page address

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
Street address
Mohammad Kemanshahi Hospital, Helal Ahmar Ave
City
Kermanshah
Postal code
Phone
00
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