Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

The comparative study of incidence of lens opacity between Osferal and Deferoxamine in major thalassemia

Protocol summary

Summary
50 patients with major thalassemia who have never received any chelator therapy but been candidate for that, are selected. All the patients go through examinations by an ophthalmologist, and those having any lens opacity will be excluded. Then the patients will be divided into two 25 membered groups, and each group will receive one of the chelators randomly. All the patients will go through re-examinations after one year, with the results of the both groups compared. In the case of having less lens opacity in osferal group, the drug could be prescribed much more safely.

General information

Acronym
IRCT registration information
IRCT registration number: **IRCT201110087677N1**
Registration date: **2011-10-16, 1390/07/24**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**
Registration date
2011-10-16, 1390/07/24

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
Kermanshah University of Medical Sciences

Expected recruitment start date
2010-12-22, 1389/10/01
Expected recruitment end date
2011-12-22, 1390/10/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The comparative study of incidence of lens opacity between Osferal and Deferoxamine in major thalassemia

Public title
The comparison of eye side effects of Osferal and Deferoxamine in patients with major thalassemia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: children having major thalassemia , being candidate for chelator therapy because of iron overload Exclusion criteria: diabetes mellitus and rheumatologic diseases, any lens disease or chelator therapy before the study
Age
From **1 year** old to **14 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **50**
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

The research and technology vice of KUMS

Street address

building no:2, shaheed beheshti Blvd., KUMS

City

Kermanshah

Postal code

Approval date

2010-06-28, 1389/04/07

Ethics committee reference number

7/711/1765/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

Lens opacity

Timepoint

After one year

Method of measurement

Ophthalmologic examinations

Secondary outcomes

1

Description

Age- Gender- Family history

Timepoint

One year

Method of measurement

Answer sheet

Intervention groups

1

Description

Intervention:In this group, 25 patients are put on a new irainian drug e; Osferal, and then it's side effect that is "lens opacity", will be compared with that of the control group.

Category

Treatment - Drugs

2

Description

Control:Based on the present policy, 25 patients who receive Deferoxamine and have a known percent of "lens opacity", are considered as the control group.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Thalassemia centre

Full name of responsible person

Reza Akramipoor

Street address

Imam Reza hospital, 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

Dr. Farid Najafi

Street address

Building no:2, shahid Beheshti blvd., Kums

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

Imam Reza hospital, KUMS

Full name of responsible person

Vahid Falahati

Position

Resident of pediatrics

Other areas of specialty/work

Street address

Imam Reza hospital, KUMS

City

Kermanshah

Postal code

Phone

+98 83 1427 6333

Fax

Email

vahidfalahati89@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Imamreza hospital, KUMS

Full name of responsible person

Mohammadreza Golpayegani

Position

Pediatric oncologist

Other areas of specialty/work

Street address

Imamreza hospital, KUMS

City

Kermanshah

Postal code

Phone

+98 83 1427 6333

Fax

Email

golpayegani@kums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Vahid Falahati

Position

pediatric resident

Other areas of specialty/work

Street address

Imam Reza hospital Kermanshah

City

Kermanshah

Postal code

Phone

+98 83 1427 6333

Fax

Email

vahidfalahati89@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