Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
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Iran (Islamic Republic of)
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+98 83 1427 6331
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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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Pediatric oncologist

Other areas of specialty/work

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Person responsible for updating data

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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