Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the efficacy and safety of Nanojade twice daily versus Nanojade once daily in transfusion-dependent thalassemia patients

Protocol summary

Study aim
Evaluating the efficacy and safety of twice daily adminitration of Nanojade versus once daily in blood transfusion dependent beta-thalassemia patients

Design
Phase 2-3, Parallel, randomized clinical trial on 56 blood transfusion dependent beta-thalassemia patients

Settings and conduct
In this study, patients with beta-thalassemia major dependent on blood transfusion referred to the thalassemia center of Bu-Ali Sina Hospital in Sari, who use Nanojade compound once a day with a dose of 14 to 20 mg per day for iron removal, but their serum ferritin is higher than 2500, or because of gastrointestinal complications, they are unable to take Nanojade with the mentioned dose and have ferritin higher than 2500 ng/dL, are selected and the drug is prescribed for them with the same dose but twice a day for one year. The control group will continue to take the drug once a day.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age over 2 years Beta thalassemia major patients dependent on blood transfusion under single-drug treatment with the iron chelator drug, Nanojade, for at least 6 months and ferritin above 2500 ng/dL or a patient with gastrointestinal side effects of drug use and ferritin above 2500 ng/dL Exclusion criteria: Unwillingness to participate in the study Failure to take medication correctly Complications leading to drug discontinuation

Intervention groups
Intervention group Nanojade product of Nanohayat company twice daily 14 to 20 mg per day. The control group consists of taking Nanojade product of Nanohayat company once daily, 14 to 20 mg per day.

Main outcome variables
Liver Iron Concentration (LIC), Serum Ferritin, Heart and Liver iron load using T2-star

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20100110003032N3**
Registration date: **2023-02-28, 1401/12/09**
Registration timing: **prospective**

Last update: **2023-02-28, 1401/12/09**
Update count: **0**

Registration date
2023-02-28, 1401/12/09

Registrant information

Name
Hossein Karami
Name of organization / entity
Mazandaran university of medical sciences
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-03-06, 1401/12/15

Expected recruitment end date
2024-03-05, 1402/12/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the efficacy and safety of Nanojade twice daily versus Nanojade once daily in transfusion-dependent thalassemia patients

Public title
Investigating the efficacy and safety of twice daily Nanojade in transfusion-dependent thalassemia patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age 2 years and older Blood transfusion-dependent major beta-thalassemia Under treatment with single iron chelator for at least 6 months and ferritin above 2500 ng/dL or patient with gastrointestinal side effects and ferritin above 2500 nd/dL

Exclusion criteria:
Unwillingness to participate in the study

Age
From **2 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **56**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization method: simple randomization Randomization Unit: Individual Randomization tool: table of random numbers

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
Ethics Committee of Mazandaran University of Medical Sciences

Street address
Pasdaran Blvd , Boali Sina Hospital

City
Sari

Province
Mazandaran

Postal code
4717844718

Approval date
2023-01-04, 1401/10/14

Ethics committee reference number
IR.MAZUMS.REC.1401.463

Health conditions studied

1

Description of health condition studied
Major beta-thalassemia

ICD-10 code
D56.1

ICD-10 code description
Beta thalassemia

Primary outcomes

1

Description
Liver Iron Concentration (LIC) mg Fe/g

Timepoint
Before starting the intervention and 6-12 months after the intervention

Method of measurement
Liver biopsy

Secondary outcomes

1

Description
Serum Urea concentration

Timepoint
Monthly after start of intervention until 12 month

Method of measurement
Serum biochemistry

2

Description
Drug side effects

Timepoint
At the start of intervention until end of intervention

Method of measurement
Patient report

3

Description
Serum Ferritin

Timepoint
At the start of intervention until end of intervention

Method of measurement
Serum biochemistry assay

4

Description

Serum Creatinine concentration (mg/dL)

Timepoint

Monthly after start of intervention until 12 month

Method of measurement

Serum biochemistry assay

5

Description

Serum Calcium concentration (mg/dL)

Timepoint

Monthly after start of intervention until 12 month

Method of measurement

Serum biochemistry assay

6

Description

Serum Phosphor concentration (mg/dL)

Timepoint

Monthly after start of intervention until 12 month

Method of measurement

Serum biochemistry assay

7

Description

Serum Alanine Aminotransferase concentration (mg/dL)

Timepoint

Monthly after start of intervention until 12 month

Method of measurement

Serum biochemistry assay

8

Description

Serum Aspartate Aminotransferase (mg/dL)

Timepoint

Monthly after start of intervention until 12 month

Method of measurement

Serum biochemistry assay

9

Description

Serum Alkaline Phosphates (mg/dL)

Timepoint

Monthly after start of intervention until 12 month

Method of measurement

Serum biochemistry assay

10

Description

Serum Bilirubin concentration (mg/dL)

Timepoint

Monthly after start of intervention until 12 month

Method of measurement

Serum biochemistry assay

Intervention groups

1

Description

Intervention group: 14 to 20 mg of Nanojade, product of Nanohayat company, twice daily for 12 months

Category

Treatment - Drugs

2

Description

Control group: 14 to 20 mg of Nanojade, product of Nanohayat company, once daily for 12 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Bu-Ali Sina Hospital

Full name of responsible person

Hossein Karami

Street address

Bu-Ali Sina Hospital, Pasdaran Blvd., Sari, Mazandaran, Iran

City

Sari

Province

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4815838477

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hokarami@mazums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Hossein Karami

Street address

Mazandaran University of Medical Sciences, Valiasr Highway

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Email

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Grant name

Grant code / Reference number

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

Title of funding source
Mazandaran University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Mazandaran University of Medical Sciences

Full name of responsible person
Hossein Karami

Position
Assistant Professor of Pediatric Hematology and Oncology

Latest degree
Subspecialist

Other areas of specialty/work
Pediatrics

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Mazandaran thalassemia research center, Bu-Ali Sina Hospital, Sari

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Person responsible for scientific inquiries

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Hossein Karami

Position
Associate Professor

Latest degree
Subspecialist

Other areas of specialty/work
Pediatrics

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Person responsible for updating data

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Position
Assistant Professor of Pediatric Hematology and Oncology

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Subspecialist

Other areas of specialty/work
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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Main outcome data can be obtained after sending the request to the principal investigator. Patients personal data will be anonymous.

When the data will become available and for how long

6 months after publication

To whom data/document is available

Investigators from university and scientific organizations

Under which criteria data/document could be used

Data could be used for verification of the study and secondary analysis

From where data/document is obtainable

It will be possible to receive data by sending an e-mail request to the main researcher, Dr. Hossein Karami, Thalassemia Center of Bu-Ali Sina Hospital, Sari. Email: hokarami@mazums.ac.ir

What processes are involved for a request to access data/document

The request will be reviewed by the main researcher after receiving it, and the data will be accessible up to one month after sending the request, if approved.

Comments