

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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 administration 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

Country

Iran (Islamic Republic of)

Phone

+98 15 1223 4506

Email address

hokarami@mazums.ac.ir

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 ng/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, Pasharan Blvd., Sari,
Mazandaran, Iran
City
Sari
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Mazandaran
Postal code
4815838477
Phone
+98 11 3334 3014
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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
City
Sari
Province
Mazandaran
Postal code
4815733971
Phone
+98 11 3304 4000
Email
pajhoheshi@mazums.ac.ir
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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Full name of responsible person
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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Fax

Email
hokarami@mazums.ac.ir

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