Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of N-acetyl cysteine on platelet aggregation in splenectomized non-transfusion dependent thalassemia patients

Protocol summary

Study aim

Determining the effect of 600 mg per day N-acetylcysteine tablet compared to not receiving the drug on the anticoagulant panel with crossover method in non-transfusion dependent thalassemia patients who underwent splenectomy

Design

A controlled, crossover groups, single-blind, randomized, phase 3 clinical trial on 20 patients. Simple randomization will be done using an envelope containing sheets with A and B letters.

Settings and conduct

Patients referring to the Thalassemia Research Center of Bu Ali Hospital who meet the inclusion criteria are divided into two groups of A and B by simple randomization. Group A receive N-acetylcysteine and group B is without medication. After one month, the group A will not receive medication and group B recieves N-acetylcysteine. The only person responsible for conducting the laboratory tests is considered blind. 5 cc of blood samples will be obtained from the patients at the beginning of the study, one month later and at the end of the second month.

Participants/Inclusion and exclusion criteria

All non-transfusion-dependent β-thalassemia patients over 18 years of age who underwent splenectomy and are treated with aspirin will be included in the study

Intervention groups

The patients are randomly divided into two groups: A, who take n-acetylcysteine orally at a dose of 10 mg per body weight (one 600 mg tablet per day) for one month, and B (without medication during the first month). Then, group B will receive the n-acetylcysteine in a cross-over manner in the second month, and group A will be without drug. The washout period is one week.

Main outcome variables

The primary outcome is a reduction of at least 50% in the anticoagulant panel, and the secondary outcomes are a reduction in factor 5 Leiden, protein c and s, antithrombin 3, and lupus anticoagulant.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100110003032N4**
Registration date: **2023-10-14, 1402/07/22**
Registration timing: **registered_while_recruiting**

Last update: **2023-10-14, 1402/07/22**
Update count: **0**

Registration date

2023-10-14, 1402/07/22

Registrant information

Name

Hossein Karami

Name of organization / entity

Mazandaran university of medical sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-21, 1402/01/01

Expected recruitment end date

2024-03-19, 1402/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of N-acetyl cysteine on platelet aggregation in splenectomized non-transfusion dependent thalassemia patients

Public title
The effect of N-acetyl cysteine on platelet aggregation in splenectomized non-transfusion dependent thalassemia patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Beta thalassemia Non-transfusion dependent Splenectomy Age above 18 years Under Aspirin therapy

Exclusion criteria:
Age less than 18 years Simultaneous consumption of other antioxidants such as vitamin C and E Diabetes Irregular use of N-acetylcysteine

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Investigator

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description
This study is a randomized clinical trial in which patients are assigned to intervention and control groups by simple randomization method. Using an envelope containing 20 sheets containing 10 A code (intervention) and 10 B code (control), patients are randomly divided into intervention and control groups. The intervention group will receive N-acetylcysteine and the control group will not receive medication. After one month, people in the intervention group will not receive medication and people in the control group will receive N-acetylcysteine.

Blinding (investigator's opinion)
Single blinded

Blinding description
The only person responsible for conducting the lab tests is blind about the use or non-use of the drug by the patients

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Commitee of Mazandaran University of Medical Sciences

Street address
Vica chancellor for Research and Technology, Moallem square, Sari

City
Sari

Province
Mazandaran

Postal code
4712855689

Approval date
2022-11-30, 1401/09/09

Ethics committee reference number
IR.MAZUMS.REC.1401.440

Health conditions studied

1

Description of health condition studied
Beta thalassemia

ICD-10 code
D56.1

ICD-10 code description
Beta thalassemia

Primary outcomes

1

Description
Reduction of at least 50% in anticoagulation panel

Timepoint
At the beginning of the study, one month later and the end of the second month

Method of measurement
Laboratory tests including: Factor V Leiden; c and s proteins; antithrombin 3; Lupus Anticoagulant

Secondary outcomes

1

Description
Factor V Leiden

Timepoint
Upon entering the study, 1 month and 2 months later

Method of measurement
Blood test

2

Description
C and S protein

Timepoint
Upon entering the study, 1 month and 2 months later
Method of measurement
Blood test

3

Description
Antithrombin 3
Timepoint
Upon entering the study, 1 month and 2 months later
Method of measurement
Blood test

4

Description
Lupus anticoagulant
Timepoint
Upon entering the study, 1 month and 2 months later
Method of measurement
Blood test

Intervention groups

1

Description
Intervention group: Patients are randomly divided into two groups: A, who recieves n-acetylcysteine orally at a dose of 10 mg per body weight (one 600 mg tablet per day) for one month.
Category
Treatment - Drugs

2

Description
Control group: Group B (control) is without medication during the first month. Then, group B will receive the n-acetylcysteine in a cross-over manner in the second month, and group A will be without drug.
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 Boulevard, Sari
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Dr. Pedram Ebrahimnejad
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Vice chancellor for Research and Technology, Moallem Square, Sari, Iran
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Web page address
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
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatric Hematology and oncologist

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Person responsible for updating data

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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
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Part of the data is accessible
When the data will become available and for how long
Starting in January 2025
To whom data/document is available
Everybody
Under which criteria data/document could be used
Systematic review articles
From where data/document is obtainable
Contact Dr. Hossein Karami. E-mail: hokarami@mazums.ac.ir
What processes are involved for a request to access data/document
After contact, information is sent within a few days
Comments