

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 receives 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  $\beta$ -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)

##### Phone

+98 15 1223 4506

##### Email address

hokarami@mazums.ac.ir

##### 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 Committee 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 receives 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, Pasharan Boulevard, Sari

#### **City**

Sari

#### **Province**

Mazandaran

#### **Postal code**

4815838477

### **Phone**

+98 11 3334 3014

### **Email**

hokarami@mazums.ac.ir

## **Sponsors / Funding sources**

### **1**

### **Sponsor**

#### **Name of organization / entity**

Mazandaran University of Medical Sciences

#### **Full name of responsible person**

Dr. Pedram Ebrahimnejad

#### **Street address**

Vice chancellor for Research and Technology,  
Moallem Square, Sari, Iran

#### **City**

Sari

#### **Province**

Mazandaran

#### **Postal code**

4817844718

#### **Phone**

+98 11 3325 7230

#### **Fax**

+98 11 3326 1244

#### **Email**

p.ebrahimnezhad@mazums.ac.ir

#### **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

**Street address**

Buali Hospital, Pasdaran Boulevard, Sari

**City**

Sari

**Province**

Mazandaran

**Postal code**

4815838477

**Phone**

+98 11 3334 3012

**Fax****Email**

hokarami@mazums.ac.ir

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Dr. Mohaddeseh Momeni

**Position**

Resident of Pediatrics

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Pediatrics

**Street address**

BuAli Hospital, Pasdaran Boulevard, Sari

**City**

Sari

**Province**

Mazandaran

**Postal code**

4815838477

**Phone**

+98 11 3334 3012

**Email**

m.momeni@mazums.ac.ir

**Person responsible for updating data****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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4817844718

**Phone**

+98 11 3325 7230

**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**

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**