

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The Amount of Folic Acid and Homocysteine in Patients With Major Beta Thalassemia Recipient of Blood over 2 Years

Protocol summary

Summary

The aim of this study was to evaluate the role of folic acid in the treatment of patients with thalassemia major. In this study 40 patients over two years for at least 6 months, blood recipients who received folic acid supplements are examined. A blood sample at baseline and one month after cessation of folic acid a sample taken from the patient and folic acid and homocysteine levels in the blood can be measured and compared. This is a before and after study. It means that the control group will be the same with the case group. Over 2 years were enrolled and pregnant and lactating women are excluded. The study intervention is discontinued folic acid supplements and folic acid and homocysteine levels as the primary outcome variable.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016011425989N2**

Registration date: **2016-03-14, 1394/12/24**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-03-14, 1394/12/24

Registrant information

Name

Bahram Darbandi

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 3336 9061

Email address

darbandi45@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Guilan University of Medical Sciences

Expected recruitment start date

2015-03-20, 1393/12/29

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Amount of Folic Acid and Homocysteine in Patients With Major Beta Thalassemia Recipient of Blood over 2 Years

Public title

The Impact of Folic Acid in The Treatment of Major - Thalassemia

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria: Patients over Two Years of Age with Thalassemia Major Blood Recipient who Received Folic Acid Supplements for at Least 6 Months Exclusion Criteria: Under two Years; Pregnant Women; Lactating Women

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked
No information

Sample size
Target sample size: 40

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features
This is a before and after study. It means that the control group will be the same with the case group.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Guilan University of Medical Sciences

Street address

10th KM of Tehran Road

City

Rasht

Postal code

Approval date

2015-11-20, 1394/08/29

Ethics committee reference number

ir.gums.rec.1394.35

Health conditions studied

1

Description of health condition studied

Beta Thalassemia

ICD-10 code

D56.1

ICD-10 code description

Thalassemia(anemia) (disease)- major D56.1

Primary outcomes

1

Description

Serum folic acid levels

Timepoint

Supplements before and one month after stopping it

Method of measurement

In terms of micrograms per liter and by

chemiluminescence

2

Description

Serum homocysteine level

Timepoint

Supplements before and one month after stopping it

Method of measurement

In terms of micromoles per liter and by chemiluminescence

Secondary outcomes

empty

Intervention groups

1

Description

In this study one milligram of folic acid supplements daily for patients already taking a number were cut off for a month. In this review we have one study group.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasht 17th Shahrivar Hospital

Full name of responsible person

Dr.Hajar Hemmati

Street address

Rasht-17th Shahrivar Hospital

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Guilan University of Medical Sciences

Full name of responsible person

Dr.Rasul Tabari

Street address

Rasht- Gas Square

City

Rasht

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, Guilan 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**

Medical Sciences of Guilan University

Full name of responsible person

Dr.Hajar.Hemmati

Position

Resident Assistance of Pediatrics

Other areas of specialty/work**Street address**

17th shahrivar hospital

City

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

Medical Sciences of Guilan University

Full name of responsible person

Dr.Bahram Darbandi

Position

Specialty pediatric cancer and blood/Assistant Professor

Other areas of specialty/work**Street address**

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Postal code**Phone**

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darbandi45@gums.ac.ir

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Medical Sciences of Guilan University

Full name of responsible person

Dr.Hajar.Hemmati

Position

Assistant Professor of Pediatrics

Other areas of specialty/work**Street address**

17th Shahrivar

City

Rasht

Postal code**Phone**

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Fax**Email****Web page address****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