

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Evaluation of the effect of folate supplement on red blood cells indices and the sense of well being of children suffering from minor thalassemia

Protocol summary

Summary

Aim of this study is evaluation of the effect of folate supplement on red blood cells indices and sense of well being of children suffering from minor thalassemia. Inclusion criteria: children 5-15 years of age with thalassemia. Exclusion criteria: iron deficiency anemia and thalassemia minor, underlying disease, lack of compliance to medication. This study is clinical trials and double blind. 290 patients with minor thalassemia will enter this study. We check all patients for complete blood cells and ferritin and red blood cells and Red blood cell distribution width. We will divide patients in two groups. We prescribe Folic acid daily in morning fasting for six months in intervention group. We prescribe placebo daily in morning fasting for six months in control group. We check complete blood cells and ferritin and red blood cells and Red blood cell distribution width after six months. We check well being of children for Psychological testing in first and end of study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017051520258N48**
Registration date: **2017-05-30, 1396/03/09**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-05-30, 1396/03/09

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Arak University of Medical Sciences

Expected recruitment start date

2017-03-18, 1395/12/28

Expected recruitment end date

2019-03-19, 1397/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of folate supplement on red blood cells indices and the sense of well being of children suffering from minor thalassemia

Public title

Effect of folate supplement on sense of well being of children suffering from minor thalassemia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: children 5-15 years of age with thalassemia Exclusion criteria: iron deficiency anemia and thalassemia minor, underlying disease, lack of compliance to medication

Age

From **5 years** old to **15 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **290**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double 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 Arak University Of Medical Sciences

Street address

Dr Mohammad Rafiei, Vice chancellor for research,
Payambar azam complex, Basij squire, Sardasht, Arak

City

Arak

Postal code

38149578558

Approval date

2017-03-15, 1395/12/25

Ethics committee reference number

IR.ARAKMU.REC.1395.399

Health conditions studied

1

Description of health condition studied

minor thalassemia

ICD-10 code

D56.9

ICD-10 code description

Thalassaemia, unspecified

Primary outcomes

1

Description

well being of children

Timepoint

start and six months after study

Method of measurement

Psychological testing

2

Description

complete blood cells

Timepoint

first and 6 months after

Method of measurement

Blood test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: We prescribe 1 milligram Folic acid daily in morning fasting for six months in intervention group.

Category

Treatment - Drugs

2

Description

control group: We prescribe placebo daily in morning fasting for six months in control group.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amirkabir hospital

Full name of responsible person

Dr fatemeh dorreh

Street address

Amirkabir hospital, Parastar square, Arak

City

Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Arak University of
Medical Sciences

Full name of responsible person

Dr Mohammad Rafiee

Street address

Vice chancellor for research, Payambar Azam
Complex, Basij square, Sardasht, Arak

City
Arak

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, Arak 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
Arak University of Medical Sciences

Full name of responsible person
Dr Aziz Eghbali

Position
Faculty

Other areas of specialty/work

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Person responsible for updating data

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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