Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 feritin 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 feritin 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

Iran (Islamic Republic of)

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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 squre, 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
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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