Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effectiveness of Neurobion in improving the general health of patients with thalassemia major referred to the hospital

Protocol summary

Study aim

Evaluation of the effect of Neurobion in patients with Thalassemia major

Design

یک کارآزمایی بالینی ، تصادفی ، کورکورانه و کنترل شده با طرح گروه موازی 40 بیمار ، که از اکتبر 2018 تا سپتامبر 2019 ثبت نام شدند و به مدت یک سال دنبال شدند.

Settings and conduct

A clinical trial, Random, blind and controlled with a parallel group design of 40 patients, who were registered from October 2018 to September 2019 and followed for one year.

Participants/Inclusion and exclusion criteria

All patients with Thalassemia major over 10 years of age

Intervention groups

The first group is treated with Thalassemia for 6 months, including regular transfusion, calcium and zinc sulfate, and folic acid in the presence of Neurobion that Neurobion will be given as an intramuscular injection every two weeks and then a one-month wash-out period to eliminate the possible effects of the drug.And then they will be treated for Thalassemia without Neurobion for the second 6 months and they will take a placebo and we will do the opposite for the second group.In this way, the first 6 months will be treated with Thalassemia without Neurobion and they will take a placebo and then the second 6 months will be treated with Thalassemia in the presence of Neurobion.Patients who will be treated with Neurobion will have a monthly CBC test after receiving Neurobion, Patients will complete two types of checklists during treatment, including a questionnaire containing demographic information and study variables, including: age, sex, blood transfusion intervals, history of splenectomy, type of supplement received, type of chelator and CBC test for Hb changes.

Main outcome variables

Change in the quality of life of patients with Thalassemia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180602039941N1**
Registration date: **2020-09-29, 1399/07/08**
Registration timing: **retrospective**

Last update: **2020-09-29, 1399/07/08**
Update count: **0**

Registration date

2020-09-29, 1399/07/08

Registrant information

Name

Fateme Sahamipourdehghan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3464 2380

Email address

f.sahamipour@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-22, 1397/10/01

Expected recruitment end date

2019-12-22, 1398/10/01

Actual recruitment start date

2018-12-22, 1397/10/01

Actual recruitment end date

2019-12-22, 1398/10/01

Trial completion date

2020-07-22, 1399/05/01

Scientific title

The effectiveness of Neurobion in improving the general health of patients with thalassemia major referred to the hospital

Public title
The effect of Neurobion in the treatment of Thalassemia
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
All patients with Thalassemia major over 10 years of age
Exclusion criteria:
Patients who do not wish to participate in this plan Patients with Hepatitis and Renal failure Patients with Thalassemia major under 10 years of age Patients with alloimmunization Patients who do not receive Zinc sulfate, Calcium and Folic acid
Age
From **10 years** old
Gender
Both

Phase
0
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **40**
Actual sample size reached: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Children with betaThalassemia major over 10 years of age willing to cooperate and sign informed written consent to participate in the study having at least two years of transfusion history at least 20 days after the last transfusion at the time of blood transfusion specific treatment with Deferoxamine) Neurobion supplementation with Deferoxamine
Blinding (investigator's opinion)
Double blinded
Blinding description
The researcher, participants, physician, and statistical analyst were blinded in this study, meaning that none of the neurons consumed by the patients were known.
Placebo
Used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Amirkabir Hospital Clinical Research Development Center
Street address
Shahid Shiroudi St. - Parstar Sq. - Amirkabir Hospital, Arak
City
Arak
Province
Markazi
Postal code
۳۸۱۹۶۹۳۳۶۵
Approval date
2018-02-26, 1396/12/07
Ethics committee reference number
IR.ARAKMU.REC.1396.301

Health conditions studied

1

Description of health condition studied
Major Thalassemia
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Score of physical symptoms, anxiety, sleep disorder and depression in questionnaire number two
Timepoint
Measurement of monthly hemoglobin after neurobion injection
Method of measurement
Blood test and questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Twenty Patients with Thalassemia major over 10 years of age who receive Neurobion
Category
Rehabilitation

2

Description
Control group:Patients with Thalassemia major over the age of 10 receive a placebo
Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Amirkabir hospital

Full name of responsible person
Fateme sahamipour dehqan

Street address
Arak - Shahid Shiroudi St. - Parstar Square - Amirkabir Hospital Arak

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+98 86 3313 6055

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it@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Vice President for Research and Technology

Street address
Arak city, University of Medical Sciences, University Complex of the Great Prophet (PBUH) Vice Chancellor for Research and Technology

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Province
Markazi

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38481-76341

Phone
+98 86 3417 3639

Email
research@arakmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Arak 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
Arak University of Medical Sciences

Full name of responsible person
Fateme sahamipourdehqan

Position
Medical student

Latest degree
A Level or less

Other areas of specialty/work
Medical Education

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Amirkabir hospital in Arak- Parstar square-Shahid Arak- city street

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Person responsible for scientific inquiries

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Full name of responsible person
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Latest degree
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Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Fateme sahami pour dehghan

Position

دانشجوی پزشکی عمومی

Latest degree

A Level or less

Other areas of specialty/work

Medical Education

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Lack of access to complete personal information

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is 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

After identifying individuals, some of the participants' personal data such as age, marital status, etc. will be shared in order to control confounding variables.

When the data will become available and for how long

Access period starts one year after the results are published

To whom data/document is available

Researchers and students who need data for related research projects.

Under which criteria data/document could be used

Use of the present data is subject to the permission of all project partners. All statistical analyzes will be applicable to the data.

From where data/document is obtainable

Fateme Sahami Pour Deheqan

What processes are involved for a request to access data/document

With the permission of me Within one month, the data of this study will be sent to the applicant in an SPSS file.

Comments