Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jul 2026

Comparison of the efficacy and safety of herbal product (Resveratrol) with Hydroxyurea (HU) in non- transfusion- dependent B-thalassemia-intermedia

Protocol summary

Summary

Objective: the aim of this study was evaluation and comparison of the efficacy and safety of herbal product (Resveratrol) with HU in non- transfusion- dependent B-thalassemia-intermedia. Inclusion criteria: non transfused in the 6 months ago; patients who did not receive HbF- inducer in the 6 months ago; normal liver or kidney function tests; normal CBC test. Exclusion criteria: Patients will be excluded from this trial if they have one of the following criteria: Abnormal liver or kidney function tests; An alanine aminotranferase (ALT) level and aspartate aminotransferase (AST) greater than 3 fold; serum creatinine level above the upper limit of normal; they can leave the study when they want. Target sample size was sixty. Intervention studied was Resveratrol 1 gr/day orally, Hydroxyurea 10-15(mg/kg/day). Variation in Hb, HbF (every month for 6 months) and need to transfusion was evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014112320051N2**
Registration date: **2015-08-19, 1394/05/28**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2015-08-19, 1394/05/28

Registrant information

Name

Mehran Karimi

Name of organization / entity

Hematology Research Center, Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Shiraz University of Medical Sciences

Expected recruitment start date

2015-08-23, 1394/06/01

Expected recruitment end date

2015-10-23, 1394/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy and safety of herbal product (Resveratrol) with Hydroxyurea (HU) in non- transfusion-dependent B-thalassemia-intermedia

Public title

Evaluation and comparison of the efficacy and safety of Resveratrol withHydroxyurea (HU) in B-thalassemia-intermedia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: non transfused in the 6 months ago; patients who did not receive HbF- inducer in the 6 months ago; normal liver or kidney function tests; normal

CBC test. Exclusion criteria: Patients will be excluded from this trial if they have one of the following criteria: Abnormal liver or kidney function tests; An alanine aminotranferase (ALT) level and aspartate aminotransferase (AST) greater than 3 fold; serum creatinine level above the upper limit of normal; they can leave the study when they want

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
Convenience sampling randomization was done using block randomization

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethic Committee of Shiraz University of Medical Sciences

Street address
Shiraz University of Medical Sciences, Zand Street, Shiraz

City
Shiraz

Postal code

Approval date
2015-04-19, 1394/01/30

Ethics committee reference number
IR.SUMS.REC.1394.16

Health conditions studied

1

Description of health condition studied
Thalassemia

ICD-10 code
D56.1

ICD-10 code description
Thalassemia Intermedia

Primary outcomes

1

Description
1:HB

Timepoint
Base line,End of every month,End of study

Method of measurement
CBC

2

Description
2: HbF

Timepoint
base line,End of every month,End of study

Method of measurement
Hemoglobin Electrophoresis

Secondary outcomes

1

Description
1:Saftey

Timepoint
Base line,End of evey month,end of study

Method of measurement
Follow up,clinical examination by expert hematologist

2

Description
2:Possible gastrointestinal side effects ,including diarrhea

Timepoint
Base line,End of every month,End of study

Method of measurement
Follow up,clinical examination by expert hematologist

Intervention groups

1

Description
Intervention group 1: patients treated with HU, Resveratrol Resveratrol 1 gr/day orally, Hydroxyurea 10-15(mg/kg/day)

Category
Treatment - Drugs

2

Description
Control group: including Placebo + Hydroxyurea 10-15 mg/kg/day

Category
Placebo

3

Description
Intervention group 2: including Resveratrol 1 gr/day orally + Placebo
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hematology Research Center
Full name of responsible person
Mozhgan Rezaei
Street address
Hematology Research Center, Nemazee Hospital, Zand street, Shiraz
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Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Shiraz University of Medical Sciences
Full name of responsible person
Mehran Karimi
Street address
Hematology Research Center, Nemazee Hospital, Zand Street
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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, Shiraz 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
Hematology Research Center, Nemazee Hospital, Shiraz
Full name of responsible person
Sezaneh Haghpanah
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Assistance professor of community medicine
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Person responsible for scientific inquiries

Contact
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Person responsible for updating data

Contact
Name of organization / entity
Hematology Research Center, Nemazee Hospital, Shiraz
Full name of responsible person
Tahereh Zarei
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Msc Microbiologist
Other areas of specialty/work
Street address
Hematology Research Center, Nemazee Hospital, Zand street, Shiraz
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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