Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparing the effects of β-D-Mannuronic acid with Placebo in Myelodispelasia patients and related clinical and paraclinical parameters before and after treatment

Protocol summary

Study aim

The main target of this study is to assess the safety and efficacy of β-D-Mannuronic acid in patients suffering from Myelodispelasia syndrome.

Design

In this study which is a phase 1-2 clinical-trial, 28 patients suffering from MDS and qualify the inclusion criteria of study are choosen. In order to allocate the patients randomly into two groups of treatment and control, at first 7 blocks of 4 with C and T letters (The letters indicate the intervention and control groups) are created in each 2 patients are belonged to the intervention group and 2 to the control group). Then the blocks are randomly selected and arranged to obtain a sequential combination of 28 letters. Each letter will be placed in a sealed packet according to the obtained sequence.

Settings and conduct

28 patients over 18 years of age suffering from MDS are choose considering to inclusion criteria (patients who based on IPSS SCORE, be in high risk and intermediate group) in hematologic oncology clinic of Tehran Imam Khomeini hospital complex in first visit by oncologist. After filling the testimonial, the patients are divided to 2 control and treatment group in 1 to 1 form based on demographic information. The study will be done in random double blind form and neither patients nor investigator know the kind of consuming drug.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) Patients can be men and female , 2) Patients should be more than 18 years old , 3) Patients should be new case and their illness should be diagnosed during 3 month ago , 4) Risk grade based on IPSS SCORE in low risk or intermediated group should be IPSS low/int-1 risk 1 , 5) Patients should be able to fill the testimonial Function of liver and kidneys should be normal , 6) Patients who don't receive systemic therapies such as chemotherapy or radiotherapy , 7) The disorder should be pathological confirmation , 8) The number of blast cells in bone marrow should be less than 5% Exclusion criteria: 1) Pregnant and Lactating women , 2) Enrolling in another clinical trial study within last 4 weeks , 3) Patients who based on IPSS SCORE, be in high risk and intermediate group , 4) Suffering from other concomitant diseases such as hepatic, renal, hematological, gastrointestinal, endocrine, cardiovascular, pulmonary, neurological or cerebral disease.

Intervention groups

Treatment group (14 patients) will receive β-D-Mannuronic acid orally 1500 mg/day (three 500 mg tablets/day) with conventional drugs and Control group (14 patients)) will receive placebo with conventional drugs orally for 12 weeks.

Main outcome variables

The average of leukocytes number; The average of hemoglobin amount; The average of platelets number; The average of serum level of Lactate dehydrogenase; The average of blast cells number in peripheral blood smear

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130622013739N11**
Registration date: **2018-02-07, 1396/11/18**
Registration timing: **registered_while_recruiting**

Last update: **2018-02-07, 1396/11/18**
Update count: **0**

Registration date

2018-02-07, 1396/11/18

Registrant information

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Abbas Mirshafiey
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Tehran University of Medical Sciences
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-01-16, 1396/10/26
Expected recruitment end date
2018-05-21, 1397/02/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the effects of β-D-Mannuronic acid with Placebo in Myelodispelasia patients and related clinical and paraclinical parameters before and after treatment

Public title
Evaluation of the therapeutic efficacy of Mannuronic Acid in Myelodispelasia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients can be men and female Patients should be more than 18 years old Patients should be new case and their illness should be diagnosed during 3 month ago Risk grade based on IPSS SCORE in low risk or intermediated group should be IPSS low/int-1 risk 1 Patients should be able to fill the testimonial Function of liver and kidneys should be normal Patients who don't receive systemic therapies such as chemotherapy or radiotherapy The disorder should be pathological confirmation The number of blast cells in bone marrow should be less than 5%
Exclusion criteria:
Pregnant and Lactating women Enrolling in another clinical trial study within last 4 weeks Patients who based on IPSS SCORE, be in high risk and intermediate group Suffering from other concomitant diseases such as hepatic, renal, hematological, gastrointestinal, endocrine, cardiovascular, pulmonary, neurological or cerebral disease.
Age
From **18 years** old
Gender
Both

Phase
1-2

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **28**
Randomization (investigator's opinion)
Randomized
Randomization description
In order to allocate the patients randomly into two groups of treatment and control, at first 7 blocks of 4 with C and T letters (The letters indicate the intervention and control groups) are created in each 2 patients are belonged to the intervention group and 2 patients are belonged to the control group). Then the blocks are randomly selected and arranged to obtain a sequential combination of 28 letters. Each letter will be placed in a sealed packet according to the obtained sequence.
Blinding (investigator's opinion)
Double blinded
Blinding description
28 patients over 18 years of age suffering from MDS are choose considering to inclusion criteria (patients who based on IPSS SCORE, be in high risk and intermediate group) in hematologic oncology clinic in first visit by oncologist. After filling the testimonial, the patients are divided to 2 control and treatment group in 1 to 1 form based on demographic information. The study will be done in random double blind form and neither patients nor investigator know the kind of consuming drug.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics commitee of Tehran Imam Khomeini hospital complex
Street address
Gharib Ave, Keshavarz Blvd, Imam Khomeini hospital co
City
Tehran
Province
Tehran
Postal code
14197-33141
Approval date
2018-01-08, 1396/10/18
Ethics committee reference number
IR.TUMS.IKHC.REC.1396.4176

Health conditions studied

1

Description of health condition studied
Myelodispelasia
ICD-10 code
D46.9
ICD-10 code description
Myelodysplastic syndrome, unspecified

Primary outcomes

1

Description
The average of leukocytes number
Timepoint
At baseline and after 12 weeks of treatment
Method of measurement
Cell count by device

2

Description
The average of hemoglobin amount
Timepoint
At baseline and after 12 weeks of treatment
Method of measurement
Computing by device

3

Description
The average of platelets number
Timepoint
At baseline and after 12 weeks of treatment
Method of measurement
Cell count by device

4

Description
The average of serum level of Lactate dehydrogenase
Timepoint
At baseline and after 12 weeks of treatment
Method of measurement
ELISA

5

Description
The average of blast cells number in peripheral blood smear
Timepoint
At baseline and after 12 weeks of treatment
Method of measurement
Manual counting

Secondary outcomes

1

Description
Weakness
Timepoint
At baseline and after 12 weeks of treatment
Method of measurement
Taking history and Questionnaire

2

Description
Fatigue
Timepoint
At baseline and after 12 weeks of treatment
Method of measurement
Taking history and Questionnaire

3

Description
Frequent infections
Timepoint
At baseline and after 12 weeks of treatment
Method of measurement
Taking history and Questionnaire

4

Description
Headache
Timepoint
At baseline and after 12 weeks of treatment
Method of measurement
Taking history and Questionnaire

5

Description
heart beat
Timepoint
At baseline and after 12 weeks of treatment
Method of measurement
Taking history and Questionnaire

6

Description
Fever
Timepoint
At baseline and after 12 weeks of treatment
Method of measurement
Taking history and Questionnaire

Intervention groups

1

Description
Intervention group (14 patients): This group will receive β-D-Mannuronic acid orally 1500 mg/day (three oral 500 mg tablets/day) which is produced from the decomposition of Alginate powder (a safe and natural

substance used in food and pharmaceutical industries) for 12 weeks. It should be mentioned that Alginate powder is purchased from Sigma Corporation of U.S.A and β-D-Mannuronic acid is produced from it's decomposition in central laboratory of immunology department at School of Public Health and Institute of Health Research affiliated by Tehran University of Medical Sciences.

Category
Treatment - Drugs

2

Description
Control group (14 patients): will receive placebo with conventional drugs orally for 12 weeks.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Tehran Imam Khomeini hospital complex

Full name of responsible person
Dr seyed Reza Safaee Nodehi

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Gharib Ave, Keshavarz Blvd

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2

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Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr. Mohammad Ali Sahraeian (MD, Vice-Chancellor for Research, Tehran University of Medical Sciences)

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6th floor, central building of Tehran University of Medical Sciences, On the Corner of Keshavarz Blvd. and Qods Street, Keshavarz Blvd., Tehran, Iran

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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
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Dr. Abbas Mirshafiey

Position

Immunology PHD, Master of Immunology department in public health schoo

Latest degree
Ph.D.

Other areas of specialty/work
Immunology

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Position
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Latest degree
Specialist

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available