

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparing the effects of $\beta$ -D-Mannuronic acid with Placebo in Myelodysplasia 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  $\beta$ -D-Mannuronic acid in patients suffering from Myelodysplasia 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 chosen. 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 chosen 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  $\beta$ -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

**Name**  
Abbas Mirshafiey

**Name of organization / entity**  
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  $\beta$ -D-Mannuronic acid with Placebo in Myelodysplasia patients and related clinical and paraclinical parameters before and after treatment

**Public title**  
Evaluation of the therapeutic efficacy of Mannuronic Acid in Myelodysplasia

**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 committee 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

Myelodisplasia

#### 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  $\beta$ -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  $\beta$ -D-Mannuronic acid is produced from its 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

##### Street address

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### 2

#### Recruitment center

##### Name of recruitment center

Tehran Imam Khomeini hospital complex

##### 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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##### Web page address

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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 school

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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**Contact**

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**Full name of responsible person**

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Student Fellowship of hematology and oncology

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**Other areas of specialty/work**

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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