

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### Evaluation of the difference between two protocols of iron deficiency anemia in diabetic type II patients; given ferrous sulfate on consecutive versus alternate day

#### Protocol summary

##### Study aim

Rising hemoglobin quantity and ferritin for iron deficiency anemia in diabetic

##### Design

Clinical trial intervention group, one blind, 2 phase, random allocation

##### Settings and conduct

Measuring the amount of hemoglobin and ferritin for 50 diabetics who have iron deficiency anemia in one blind study that participants didn't know they were in which group of study.

##### Participants/Inclusion and exclusion criteria

Entry requirements: Hemoglobin level 9 to 12 and 9 to 13, in order women and men, exclusion criteria: transfusion or iron infusion

##### Intervention groups

intervention group used 2 tablets every other days in morning

##### Main outcome variables

Hemoglobin, fast blood sugar, ferritin, hemoglobin A1C

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190202042591N1**

Registration date: **2022-07-23, 1401/05/01**

Registration timing: **retrospective**

Last update: **2022-07-23, 1401/05/01**

Update count: **0**

##### Registration date

2022-07-23, 1401/05/01

##### Registrant information

Name

Bahareh Taati

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 21 7719 5321

**Email address**

bahareh\_taati@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-02-19, 1397/11/30

##### Expected recruitment end date

2020-02-19, 1398/11/30

##### Actual recruitment start date

2019-04-20, 1398/01/31

##### Actual recruitment end date

2020-03-09, 1398/12/19

##### Trial completion date

2020-03-09, 1398/12/19

##### Scientific title

Evaluation of the difference between two protocols of iron deficiency anemia in diabetic type II patients; given ferrous sulfate on consecutive versus alternate day

##### Public title

Treatment of anemia in diabetic type II patient

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

###### Inclusion criteria:

Hemoglobin level 9 to 12 and 9 to 13, in order women and men. Needless to transfusion or iron infusion. The patient has just iron deficiency anemia. A1C hemoglobin level is less than 9.

###### Exclusion criteria:

Patients who do not sign the ethical consent form.  
Patients who do not cooperate during the treatment for any reason. Patients who are moved from oral diabetes treatment to injection for any reason during anemia treatment  
Severe liver failure  
History of gastric surgery  
Diabetic patients who have different type of anemia

#### Age

From **18 years** old to **65 years** old

#### Gender

Both

#### Phase

2-3

#### Groups that have been masked

- Data analyser

#### Sample size

Target sample size: **100**

Actual sample size reached: **50**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Randomization method; Restricted Randomization in the form of permuted block randomization randomization unit; Replacement block amount of six  
How to build a sequence; Sequence allocation software can produce both blocks and Sequence Allocation concealment;  
Central Randomization: Randomized sequences are only at the disposal of the project manager, and after entering the study, the participants are randomly assigned to each of the groups.

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

Participants are defined with A, B codes in the study, where the outcome analyst does not know what type of treatment is included in each group.

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

### Secondary Ids

empty

### Ethics committees

#### 1

##### Ethics committee

###### Name of ethics committee

Ethics committee of Ahvaz University of Medical Sciences

###### Street address

Esfand street Farvardin blvd golestan town

###### City

Ahvaz

###### Province

Khuzestan

###### Postal code

6135715794

#### Approval date

2019-03-08, 1397/12/17

#### Ethics committee reference number

ir.ajums.rec.1397.924

### Health conditions studied

#### 1

##### Description of health condition studied

Iron deficiency anemia

##### ICD-10 code

D50

##### ICD-10 code description

Iron deficiency anemia

### Primary outcomes

#### 1

##### Description

Analysing the difference of Iron sulphate each day and every 2 days between those patients who are suffering from diabetes and are have low blood iron.

##### Timepoint

8weeks for group A 16weeksfor group B

##### Method of measurement

hemoglobin quantity

### Secondary outcomes

empty

### Intervention groups

#### 1

##### Description

Intervention group: given FeSo4 on alternate day

##### Category

Treatment - Drugs

#### 2

##### Description

Control group: given FeSo4 on consecutive

##### Category

Treatment - Drugs

### Recruitment centers

#### 1

##### Recruitment center

###### Name of recruitment center

Golestan hospital

###### Full name of responsible person

Bahareh Taati

###### Street address

Esfand st

###### City

Ahvaz  
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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Ahvaz University of Medical Sciences  
**Full name of responsible person**  
Dr.Mohammad Badavi  
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info@ajums.ac.ir  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
No  
**Title of funding source**  
Ahvaz university of medical science  
**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**  
Ahvaz University of Medical Sciences  
**Full name of responsible person**  
Bahareh taati  
**Position**  
Pharmacy student  
**Latest degree**  
Medical doctor

#### Other areas of specialty/work

Medical Pharmacy  
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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
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**Full name of responsible person**  
Dr.Reza Ganji  
**Position**  
Associate professor  
**Latest degree**  
Specialist  
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## Person responsible for updating data

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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**

No more information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not 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