

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jun 2026

### The effect of iron deficiency treatment on insulin resistance in women with type 2 diabetes and iron deficiency anemia

#### Protocol summary

##### Study aim

The effect of iron deficiency treatment on insulin resistance in women with type 2 diabetes and iron deficiency anemia

##### Design

Clinical trial, single group, before after study

##### Settings and conduct

The study will be conducted on women with type 2 diabetes and iron deficiency anemia, at the Shahid Beheshti Hospital, Qom. The outcomes associated with diabetes control (including Insulin resistance, Hemoglobin A1C and serum cholesterol), will be evaluated, before and after treatment of iron deficiency in 40 patients.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Woman who has been diagnosed with type 2 diabetes more than one year, Age 30-50 years, Iron deficiency anemia with hemoglobin <12; Exclusion criteria: Insulin therapy, Polymenorrhea, Pregnancy, Breast-feeding

##### Intervention groups

Intervention group: Administration of Ferrous sulfate tablet of Rouzdarou pharmaceutical co, with dosage of 325 mg, taken orally, daily, for 6 months

##### Main outcome variables

Insulin resistance; Hemoglobin A1C

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170215032587N3**

Registration date: **2018-07-22, 1397/04/31**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-07-22, 1397/04/31**

Update count: **0**

##### Registration date

2018-07-22, 1397/04/31

##### Registrant information

###### Name

Mohammad Aghaali

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 912 751 5639

###### Email address

maghaali@muq.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-05-22, 1397/03/01

##### Expected recruitment end date

2018-08-23, 1397/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of iron deficiency treatment on insulin resistance in women with type 2 diabetes and iron deficiency anemia

##### Public title

The effect of iron deficiency treatment on insulin resistance

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

###### Inclusion criteria:

More than one year has passed since the diagnosis of

type 2 diabetes Age 30-50 years Iron deficiency anemia with hemoglobin less than 12

**Exclusion criteria:**

Insulin therapy Polymenorrhea Chronic diarrhea History of gastrectomy CRP above 10 mg/L Pregnancy Breast-feeding

**Age**

From **30 years** old to **50 years** old

**Gender**

Female

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **40**

**Randomization (investigator's opinion)**

N/A

**Randomization description**

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Single

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Qom University of Medical Sciences

**Street address**

No. 83, Alley 4, Alley 1.1, Safashahr Street, Qom

**City**

Qom

**Province**

Ghoum

**Postal code**

3716987366

**Approval date**

2018-05-22, 1397/03/01

**Ethics committee reference number**

IR.MUQ.REC.1397.031

**Health conditions studied**

1

**Description of health condition studied**

Diabetes

**ICD-10 code**

E08

**ICD-10 code description**

Diabetes mellitus due to underlying condition

2

**Description of health condition studied**

Iron deficiency anemia

**ICD-10 code**

D50

**ICD-10 code description**

Iron deficiency anemia

**Primary outcomes**

1

**Description**

Insulin resistance

**Timepoint**

Six months after beginning treatment

**Method of measurement**

HOMA-IR formula

2

**Description**

Hemoglobin A1C

**Timepoint**

Six months after beginning treatment

**Method of measurement**

Blood test, High-performance liquid chromatography

**Secondary outcomes**

1

**Description**

The level of blood triglycerides

**Timepoint**

Six months after beginning treatment

**Method of measurement**

Blood test, Enzymatic photometric test

2

**Description**

The level of blood cholesterol

**Timepoint**

Six months after beginning treatment

**Method of measurement**

Blood test, Enzymatic test

**Intervention groups**

1

**Description**

Intervention group: Ferrous sulfate tablet, 325 mg, Rouzdarou pharmaceutical co, oral, daily, for 6 months

**Category**

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Shahid Beheshti Hospital

**Full name of responsible person**

Mahmoud Parham

**Street address**

Shahid Beheshti Hospital, Shahid Beheshti Blvd, Qom

**City**

Qom

**Province**

Ghous

**Postal code**

3719964797

**Phone**

+98 25 3612 2053

**Email**

Yasi.f\_90@yahoo.com

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Ghous University of Medical Sciences

**Full name of responsible person**

Hossein Saghafi

**Street address**

No. 83, Alley 4, Alley 1.1, Safashahr Street, Qom

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**Email**

hsaghafi@muq.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Ghous 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**

Ghous University of Medical Sciences

**Full name of responsible person**

Mojtaba Tavasoli

**Position**

Qom

**Latest degree**

Specialist

**Other areas of specialty/work**

Internal Medicine

**Street address**

Shahid Beheshti Hospital, Shahid Beheshti Blvd, Qom

**City**

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**Province**

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**Email**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Ghous University of Medical Sciences

**Full name of responsible person**

Mahmoud Parham

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

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**Full name of responsible person**

Mojtaba Tavasoli

**Position**

Qom

**Latest degree**

Specialist

**Other areas of specialty/work**

Internal Medicine

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**City**

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**Province**

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**Postal code**

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+98 25 3612 2053

**Email**

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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**

The data are specific to this study

**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