

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 2026

### Effect of weight loss on reproductive parameters in infertile men

#### Protocol summary

##### Summary

Infertility is one of the effective and serious problems in all of communities. The range of its frequency has been increased with respect to changes in diets and lack of physical activity in recent years. Nowadays, this hypothesis arouses that weight loss through changes in diet and life style, can case improvement in infertility which resulted from obesity and relative metabolic disorders. This study carried out for assessment the effect of weight loss through a regular diet (which is accompanied by increase of physical activities) on male fertility parameters. In this study 50 qualified person (with respect to conditions which are mentioned in inclusion criteria and after the omission of some person with respect to exclusion criteria) were selected and primary information, serological experiments (FSH- LH- TSH- PRC- Test- TG- Cholesterol- LDL- HDL), and sperm analysis according to WHO standards which 5 days have left from the last sperm discharge, will be carried out in two times (before and after diet). A suitable diet along with enough physical activity is considered for all of patients. At the end of 6 month, due to investigation of effectiveness of intervention in improvement of male semen parameters, laboratory assessment will be measured again.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138902051760N5**

Registration date: **2010-11-04, 1389/08/13**

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

Last update:

Update count: **0**

##### Registration date

2010-11-04, 1389/08/13

##### Registrant information

##### Name

Nargess Gholizadeh Pasha

##### Name of organization / entity

Fatemehzahra Infertility Reproductive Health Research Center, Babol University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3236 2282

##### Email address

zahra@mubabol.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for Research and Technology, Babol University of Medical Sciences

##### Expected recruitment start date

2010-07-23, 1389/05/01

##### Expected recruitment end date

2011-02-20, 1389/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of weight loss on reproductive parameters in infertile men

##### Public title

Effect of weight loss on reproductive parameters in infertile men

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Infertile men with BMI>25 who have passed more than one year of regular Coitus. Exclusion criteria: Men who are addicted to Cigarette, alcohol and

narcotic; Men who have chronic illness during last three weak; Men who uses certain drugs; Men who suffer from varicocele, Obstruction of vas deferens, absence of Testis or any organic change in reproductive system and also azoospermic or severe oligospermic patients (below 5 million sperm count).

#### **Age**

From **25 years** old to **45 years** old

#### **Gender**

Male

#### **Phase**

N/A

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **50**

#### **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**

The ethics committee of Babol University of Medical Sciences

###### **Street address**

Gangafroz Avenue

###### **City**

Babol

###### **Postal code**

###### **Approval date**

2010-07-12, 1389/04/21

###### **Ethics committee reference number**

1016

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

Body Mass Index

##### **ICD-10 code**

E66

##### **ICD-10 code description**

Obesity

#### **2**

##### **Description of health condition studied**

Male infertility

##### **ICD-10 code**

N46

##### **ICD-10 code description**

Male infertility

### **Primary outcomes**

#### **1**

##### **Description**

Weight Loss

##### **Timepoint**

Monthly for six months

##### **Method of measurement**

BMI Value

#### **2**

##### **Description**

Sperm Count

##### **Timepoint**

After six months

##### **Method of measurement**

Laboratory

#### **3**

##### **Description**

Sperm Motility

##### **Timepoint**

After six months

##### **Method of measurement**

Laboratory

#### **4**

##### **Description**

Sperm morphology

##### **Timepoint**

After six months

##### **Method of measurement**

Laboratory

#### **5**

##### **Description**

Liquid semen Volume

##### **Timepoint**

After six months

##### **Method of measurement**

Laboratory

### **Secondary outcomes**

#### **1**

##### **Description**

Effect of weight loss on serum hormonal parameters (FSH-LH-TEST- HDL- LDL, ...) and test the semen

**Timepoint**

6 months

**Method of measurement**

Laboratory (hormone measurement techniques appropriate for each test)

**Intervention groups****1****Description**

Appropriate diet for weight loss (with allocation of food calories 500kcal/day less than the recommended standard for each individual based on age and physical activity), Increase physical activity (daily one hour daily exercise more than average, including: walking fast, soft exercise and ...)

**Category**

Lifestyle

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Fatemehzahra Fertility & reproductive Health Reseach Center

**Full name of responsible person**

Marmar Firoozpour Bandepey

**Street address**

Noshirvani street

**City**

Babol

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice Chancellor for Research and Technology, Babol University of Medical Sciences

**Full name of responsible person**

Dr. Ali Bijani

**Street address**

Gangafroz Avenue

**City**

Babol

**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 and Technology, Babol 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**

Fatemehzahra Fertility & reproductive Health Reseach Center

**Full name of responsible person**

Nargess Gholizadeh Pasha

**Position**

M.A/Responsible for Public Affairs Research Center

**Other areas of specialty/work****Street address**

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Fatemehzahra Fertility & reproductive Health Reseach Center

**Full name of responsible person**

Dr. mohammad-Reza Aghajani Mir

**Position**

Urology specialist

**Other areas of specialty/work****Street address**

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**Full name of responsible person**

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**Web page address****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*