

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 2026

### Comparing the effect of two dosing regimen of testosterone gel 1%(once daily versus two divided doses) on refractory depression(MDD) in depressed men

#### Protocol summary

##### Study aim

Specific goals: -Comparison of Hamilton score changes in the two study groups -Comparison of changes in testosterone levels in the two groups studied - Determining the relationship between Hamilton score before the intervention and the change in Hamilton score after the intervention -Determining the relationship between basal testosterone levels and the Hamilton score before the intervention -Determining the relationship between basal testosterone levels and changes Hamilton score after the intervention - Determining the relationship between patients' blood testosterone levels and their age before the study

##### Design

This study is a cross-over & double-blind clinical trial. we follow 38 depressed men who are resistant to a 6 week trial of antidepressant treatments, during 12 weeks .

##### Settings and conduct

The study is performed in the psychology ward of Imam Khomeini Hospital Patients are randomly divided into two groups & They do not know in which group they are included.(A)10 grams of testosterone gel 1% once a day. (B)5 grams of testosterone gel 1% twice a day.

##### Participants/Inclusion and exclusion criteria

Including criterias : depression ( Hamilton score > 12 ) , Failure to respond to a six-week trial of antidepressants , Testosterone level below 350 ng/dl Excluding criterias :Acute phase of psychotic symptoms including tumors and delirium , Bipolar disorder ,Drug addicted , Testosterone level more than 350 ng/dl ,Suicide or attempted suicide in the last 3 months , History of prostate cancer , PSA level more than 4ng/dl , Dementia

##### Intervention groups

Patients are randomly divided into 2 groups.The first group receives their usual treatments with 10 grams of testosterone gel 1% once a day. The other group receives their usual treatments with 5 grams of

testosterone gel 1% twice a day.

##### Main outcome variables

Hamilton Score , Testosterone level

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191211045698N1**

Registration date: **2020-11-04, 1399/08/14**

Registration timing: **retrospective**

Last update: **2020-11-04, 1399/08/14**

Update count: **0**

##### Registration date

2020-11-04, 1399/08/14

##### Registrant information

##### Name

Nahid Tavakkoli Amirabadi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 4438 5027

##### Email address

nahid\_tavakoli1373@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-02-20, 1397/12/01

##### Expected recruitment end date

2020-03-20, 1399/01/01

##### Actual recruitment start date

2019-04-25, 1398/02/05

**Actual recruitment end date**

2020-07-23, 1399/05/02

**Trial completion date**

2020-10-22, 1399/08/01

**Scientific title**

Comparing the effect of two dosing regimen of testosterone gel 1%(once daily versus two divided doses) on refractory depression(MDD) in depressed men

**Public title**

Testosterone gel in Depression

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Depression(Hamilton Score =>12) Not responded to a 6-week trial of antidepressant drugs testosterone level less than 350ng/dl

**Exclusion criteria:**

Acute phase of psychotic symptoms including hallucinations and delusions Bipolar disorder drug addicted Testosterone level > 350ng/dl Suicide or attempted to suicide in the last 3 months Dementia PSA > 4ng/dl Prostate cancer history

**Age**

From **35 years** old

**Gender**

Male

**Phase**

1-2

**Groups that have been masked**

- Participant
- Data analyser

**Sample size**

Target sample size: **38**

Actual sample size reached: **38**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Sampling has been done through patients referred to psychosomatic ward of Imam Khomeini hospital who met the study's inclusion and exclusion criteria. For randomization we used permuted block randomization technique and patients divided to two groups by using the result of random number generation softwares(such as toolbox), also sampling allocation concealed in sequentially numbered, sealed and opaque envelopes

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Participants are unaware of which study group they are in also dosage and frequency the other group Received. In addition, The information will be provided to the data analyzer in groups A and B.

**Placebo**

Not used

**Assignment**

Crossover

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

vice-chancellor in research affairs-Tehran university of medical sciences

**Street address**

No. 8, Mahtab Ave., Marzdaran Blve.,Tehran Town

**City**

Tehran

**Province**

Tehran

**Postal code**

1461747851

**Approval date**

2019-03-05, 1397/12/14

**Ethics committee reference number**

IR.TUMS.VCR.REC.1397.1047

**2****Ethics committee****Name of ethics committee**

The Institute of Pharmaceutical Sciences -Tehran University of Medical Sciences

**Street address**

No. 8, Mahtab Ave., Marzdaran Blve.,Tehran Town

**City**

Tehran

**Province**

Tehran

**Postal code**

1461747851

**Approval date**

2019-06-02, 1398/03/12

**Ethics committee reference number**

IR.TUMS.TIPS.REC.1398.035

**Health conditions studied****1****Description of health condition studied**

Depression,Hypogonadism

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Depression score in Hamilton questionnaire

**Timepoint**

before the intervention and 1 month, 2 months and 3 months after the start of testosterone gel

## Method of measurement

Hamilton questionnaire

## 2

### Description

Testosterone level

### Timepoint

before the intervention and 1 month, 2 months and 3 months after the start of testosterone gel

### Method of measurement

Blood test to measure testosterone level

## Secondary outcomes

## 1

### Description

Sexual function score

### Timepoint

Before the intervention and 3 months after taking testosterone gel

### Method of measurement

IIEF questionnaire

## Intervention groups

## 1

### Description

first intervention group : Patients receiving 10 g of testosterone 1% gel once a day in addition to previous medications.

### Category

Treatment - Drugs

## 2

### Description

Seconde intervention group:Patients receiving 10 g of testosterone 1% gel divided in two dosage in addition to previous medications.

### Category

Treatment - Drugs

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Imam Khomeini hospital

#### Full name of responsible person

Nahid Tavakoli

#### Street address

Imam Khomeini complex hospital., Keshavarz Blvd.,  
Tehran

#### City

Tehran

#### Province

Tehran

#### Postal code

1419733141

#### Phone

+98 21 6658 1624

#### Email

nahid\_tavakoli1373@yahoo.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

Niyayesh Mohebi

#### Street address

Faculty of pharmacy., Tehran university of medical sciences

#### City

Tehran

#### Province

Tehran

#### Postal code

۱۴۱۷۶۱۴۴۱۱

#### Phone

+98 21 6695 4709

#### Email

niayesh\_mohebibi@yahoo.com

#### 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

Nahid Tavakoli

#### Position

Pharmacy student

#### Latest degree

A Level or less

#### Other areas of specialty/work

Medical Pharmacy

#### Street address

No. 8, Mahtab Ave., Marzdaran Blvd., Tehran

**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1461747851  
**Phone**  
+98 21 4438 5027  
**Email**  
nahid\_tavakoli1373@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Nahid Tavakoli  
**Position**  
Pharmacy student  
**Latest degree**  
A Level or less  
**Other areas of specialty/work**  
Medical Pharmacy  
**Street address**  
No. 8, Mahtab Ave., Marzdran Blvd., Tehran  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1461747851  
**Phone**  
+98 21 4438 5027  
**Email**  
nahid\_tavakoli1373@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Nahid Tavakoli  
**Position**  
Pharmacy student  
**Latest degree**  
A Level or less  
**Other areas of specialty/work**  
Medical Pharmacy  
**Street address**  
No. 8, Mahtab Ave., Marzdran Blvd., Tehran

**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
۱۴۶۱۷۴۷۸۵۱  
**Phone**  
+98 21 4438 5027  
**Email**  
nahid\_tavakoli1373@yahoo.com

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is 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

Yes - There is a plan to make this available

### Title and more details about the data/document

All personal data of the participants after unidentifying the personal individual datas, including the age of the individuals, Testosterone levels and Hamilton score before the intervention and 1 month, 2 months and 3 months after the intervention, Sexual function score before and 3 months after the intervention

### When the data will become available and for how long

6 months after the publication of the results

### To whom data/document is available

Researchers working in academic and scientific institutions

### Under which criteria data/document could be used

Please contact relevant numbers or emails before using the data

### From where data/document is obtainable

1- Nahid Tavakoli: nahid\_tavakoli1373@yahoo.com, 0098 9127972230 2- Niayesh Mohebi: niayesh\_mohebbi@yahoo.com, 0098 9121781476

### What processes are involved for a request to access data/document

Please contact relevant numbers or emails before using the data

### Comments