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_mohebbi@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., Marzdaran 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