Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effects of Hesperidin on serum homocysteine, cortisol and tryptophan kynurenine pathway in major depressive disorder

Protocol summary

Study aim
Effects of Hesperidin on serum homocysteine, cortisol and tryptophan kynurenine pathway in patients with major depressive disorder

Design
double blind randomized controlled trial

Settings and conduct
forty eight patients with major depression aged 18 to 65 years will be referred to Ziaeian hospital. They will randomly be allocated to groups, daily Hesperidin supplement or placebo daily for 8 weeks.To measure serum level of cortisol, homocysteine, tryptophan and kynurenine, 10 ml of venous blood will be collected after 10-12 hours of fasting at the beginning and at the end of the study.

Participants/Inclusion and exclusion criteria
Participants: Patients with major depression aged 18 to 65 years. inclusion criteria:having physical health based on history, no regular use of any supplements more than twice a week, two months prior the intervention, No use of drugs and any antidepressant, no citrus consumption more than 2 units per day, lack of thoughts of death and suicide, lack of mental illness except anxiety Exit criteria: Dissatisfaction of patients to continue cooperation, pregnancy and lactation, obtaining each non-compliance criterion.

Intervention groups
Intervention group: Received one capsule of 500 mg hesperidine + sertraline daily Control group:Received one capsule of 500 mg placebo + sertraline

Main outcome variables
Serum level of cortisol, tryptophan, homocysteine, kynurenine

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20090901002394N40**
Registration date: **2018-12-18, 1397/09/27**
Registration timing: **registered_while_recruiting**

Last update: **2018-12-18, 1397/09/27**
Update count: **0**

Registration date
2018-12-18, 1397/09/27

Registrant information

Name
Shima Jazayeri

Name of organization / entity
Iran University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 21 8670 4805

Email address
sjazayeri@razi.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-08-23, 1397/06/01

Expected recruitment end date
2019-08-23, 1398/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effects of Hesperidin on serum homocysteine, cortisol and tryptophan kynurenine pathway in major depressive disorder

Public title
effect of hesperidin on depression
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Willing to participate Clinical diagnosis of major depressive disorder; A score ≥15 in the 17-item Hamilton Depression Rating Scale; Age 18 – 65 years; Good health status based on medical history No dietary supplement use during the previous two months No antidepressant or steroid use Absence of benign hormone-sensitive tumors in the ovary, uterus, breast, prostate Not having thoughts about death and suicide Not having any mental illness except anxiety Do not eat citrus more than two units per day
Exclusion criteria:
Pregnancy and lactation
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **48**
Randomization (investigator's opinion)
Randomized
Randomization description
Subjects will be divided into two groups: intervention and placebo (stratified randomization) Based on age (18-40 40-65) Using 4-way permutation blocks and select blocks based on random numbers
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo and supplements will be similar in appearance and coded by someone other than the researcher. All investigators, study staff, and participants will be unaware of the allocations. The randomization code will be broken only when the statistical model of the primary and secondary results will be completed.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
ethics committee of Iran University of Medical Sciences
Street address
Shahid Hemmat Highway, next to Milad Hospital, Iran University of Medical Sciences
City
Tehran
Province
Tehran
Postal code
1449614535
Approval date
2018-03-01, 1396/12/10
Ethics committee reference number
IR.IUMS.REC 1396.9511468005

Health conditions studied

1

Description of health condition studied
Major Depressive Disorder
ICD-10 code
F32.3
ICD-10 code description
Major depressive disorder, single episode, severe with psychotic features

Primary outcomes

1

Description
serum level of cortisol
Timepoint
beginning and end of intervention
Method of measurement
ELIZA

2

Description
serum level of homocysteine
Timepoint
beginning and end of intervention
Method of measurement
ELIZA

3

Description
serum level of tryptophan
Timepoint
beginning and end of intervention
Method of measurement
ELIZA

4

Description
serum level of kynurenine
Timepoint
beginning and end of intervention
Method of measurement
ELIZA

Secondary outcomes

1

Description
physical activity
Timepoint
beginning and end of intervention
Method of measurement
IPAQ questionnaire

2

Description
energy intake
Timepoint
beginning and end of intervention
Method of measurement
Three-day food record

Intervention groups

1

Description
Control group: placebo 500mg daily for 8 week
Category
Placebo

2

Description
Intervention group: hesperidin 500mg daily foe 8 week
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Clinic of Ziaeian Hospital
Full name of responsible person
Dr Mohammad Effatpanah
Street address
Abouzar Ave, Ziaeian Hospital
City
Tehran
Province
Tehran
Postal code
1366736511
Phone
+98 21 5517 6810
Email
ziaeian@tums.ac.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr Seyed Ali Javad Moosavi
Street address
Iran university of medical sciences, Hemmat highway, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 8670 4805
Email
sh_jazayeri@tums.ac.ir
Web page address
http://iums.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Hadis Sarlak
Position
Master student in nutrition sciences
Latest degree
Bachelor
Other areas of specialty/work
Nutrition
Street address

school of public health, Iran university of medical sciences, Hemmat highway, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1449614535

Phone
+98 21 8670 4805

Email
hadis_s93@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Dr Shima Jazayeri

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

Street address
school of public health, Iran university of medical sciences, Hemmat highway, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1449614535

Phone
+98 21 8670 4805

Email
sh_jazayeri@tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Hadis Sarlak

Position
Master student in nutrition sciences

Latest degree
Bachelor

Other areas of specialty/work
Nutrition

Street address
school of public health, Iran university of medical sciences, Hemmat highway, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1449614535

Phone
+98 21 8670 4805

Email
hadis_s93@yahoo.com

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
There is no more information

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
There is no more information

When the data will become available and for how long
There is no more information

To whom data/document is available
There is no more information

Under which criteria data/document could be used
There is no more information

From where data/document is obtainable
There is no more information

What processes are involved for a request to access data/document
There is no more information

Comments