The effect of Hydro alcoholic Extract of Mentha Piperita (Mint) as a Complementary Treatment on the severity of Depressive Disorder

Protocol summary

Summary
This study was carried out to determine the effect of hydro alcoholic extract of Mentha Piperita or Mint (Lamiaceae family) as a complementary treatment on the severity of depressive disorder. This is a triple blind randomized clinical trial was carried out on depressed patients referred to Shahid Mofateh Clinic of Yasouj city during 2007-2008. A total of 120 patients were randomly divided into 5 equal groups to receive placebo, or 10 mg, 50 mg, 100 mg or 200 mg hydro alcoholic extract of Mentha Piperita for two months. After this period, the severity of depression of the patients was evaluated by BDI and DSM IV-TR criteria and compared between groups.

General information

Acronym
IRCT registration information
IRCT registration number: IRCT201011105147N1
Registration date: 2011-01-13, 1389/10/23
Registration timing: retrospective

Last update: 0
Registration date 2011-01-13, 1389/10/23

Registrant information
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Nazir Hashemi Mohammad Abad
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Yasuj University of Medical Sciences
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Recruitment status
Recruitment complete
Funding source
Yasouj University of Medical Sciences

Expected recruitment start date
2007-04-20, 1386/01/31
Expected recruitment end date
2008-04-20, 1387/02/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of Hydro alcoholic Extract of Mentha Piperita (Mint) as a Complementary Treatment on the severity of Depressive Disorder

Public title
The effect of Hydro alcoholic Extract of Mentha Piperita (Mint) as a Complementary Treatment on the severity of Depressive Disorder

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: age 18-60 years, having depressive symptoms for at least two weeks, having a similar treatment except extract Mentha Piperita
Exclusion criteria: Other psychological disorder, history of admission in psychiatry ward, receiving treatment by ECT (electroconvulsive therapy), history of using any drug except antidepressant drug by psychiatrist in this research

Age
From 18 years old to 60 years old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: 120
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Triple blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids
empty

Ethics committees

1
Ethics committee
Name of ethics committee
Yasouj University of Medical Sciences, Ethics committee
Street address
Yasouj University of Medical Sciences, Bahonar boulevard, Yasouj
City
Yasouj
Postal code
Approval date
2006-12-09, 1385/09/18
Ethics committee reference number
85918-14

Health conditions studied

1
Description of health condition studied
Depression
ICD-10 code
F32
ICD-10 code description
Depressive disorder

Primary outcomes

1
Description
Severity of depression
Timepoint
Baseline and 2 months after intervention
Method of measurement
Beck Depression Inventory (BDI) and psychiatry interview by DSM IV-TR

Secondary outcomes
empty

Intervention groups

1
Description
Oral mint capsule, 100 mg, once daily for 2 months
Category
Treatment - Drugs

2
Description
Oral mint capsule, 10 mg, once daily for 2 months
Category
Treatment - Drugs

3
Description
Oral mint capsule, 50 mg, once daily for 2 months
Category
Treatment - Drugs

4
Description
Oral mint capsule, 200 mg, once daily for 2 months
Category
Treatment - Drugs

5
Description
Placebo oral capsule, once daily for 2 months
Category
Placebo

Recruitment centers

1
Recruitment center
Name of recruitment center
Shahid Mofate Clinic of Yasouj
Full name of responsible person
Nazir Hashemi Mohammad Abad
Street address
No 19, 5 Bahonar, Oghab square, Yasouj
City
Yasouj

Sponsors / Funding sources

1
Sponsor
Name of organization / entity
Vice-chancellor for Research
Full name of responsible person
Nazir Hashemi Mohammad Abad
Street address
NO 19, 5 Bahonar, Oghab Square, Yasouj
City
Yasouj
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

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
empty

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Yasouj University of Medical Sciences
Full name of responsible person
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Assistant Professor of Psychiatry
Other areas of specialty/work
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Person responsible for updating data

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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