Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison between herb drink of Melissa and black tea in decreasing stress, anxiety and insomnia as well as increasing body`s antioxidant among hospitalized burn patients in Shahid Motahari Hospital

Protocol summary

Summary

We have designed this study to evaluate the effects of Melissa herbal drink on the reduction of stress, anxiety disorders and insomnia and also in the increasing of total body`s antioxidant level in burn patients. This study is a randomized clinical trial that has been done on 36 patients. Patient`s inclusion criterion: age of 18 to 70 years, 35% to 55% burn percentage, need of being hospitalized. Exclusion criteria: pregnancy, lactation, intention to become pregnant during the course of the study, consumption of anti-anxiety drugs or antidepressants or sedative 10 days before starting the study, diabetes, asthma, hypo- and hyper-thyroidism, depression, schizophrenia or psychosis, consumption of serotonin-reuptake inhibitors. The selected patients are divided into two groups of 18 individuals based on random number table. Then 250 cc of Melissa tea are given twice a day (mornings and evenings) to the experimental group and 250 cc of black tea are given twice a day (mornings and evenings) to the control group for 20 days. Depression, anxiety and insomnia are measured via Beck`s , Kettle and Petersburg questionnaires respectively, in both groups once in the beginning of intervention and once more after 20 days. Total antioxidant is measured via Spectrophotometry techniques in both groups once at the beginning of the trial and once more after 20 days. Afterwards the results of both groups will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201205198177N4**
Registration date: **2013-08-22, 1392/05/31**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2013-08-22, 1392/05/31

Registrant information

Name
Mohammad Javad Fatemi
Name of organization / entity
Burn Research Center of Tehran University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2013-07-06, 1392/04/15

Expected recruitment end date

2013-09-23, 1392/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between herb drink of Melissa and black tea in decreasing stress, anxiety and insomnia as well as increasing body`s antioxidant among hospitalized burn patients in Shahid Motahari Hospital

Public title
Effects of Melissa in decreasing stress, anxiety and insomnia as well as increasing body`s antioxidant
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criterion: age of 18 to 70 years, 35% to 55% burn percentage, need of being hospitalized. Exclusion criterion: pregnancy, lactation, intention to become pregnant during the course of the study, consumption of anti-anxiety drugs or antidepressants or sedative 10 days before the start of the study, diabetes, asthma, hypo- and hyperthyroidism, depression, schizophrenia or psychosis, consumption of serotonin-reuptake inhibitors drugs.
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
1-2
Groups that have been masked
No information
Sample size
Target sample size: **36**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tehran University of Medical Sciences
Street address
Central Department of Tehran University of Medical Sciences, Keshavarz Bvld
City
Tehran
Postal code
1417653761
Approval date
2013-06-02, 1392/03/12
Ethics committee reference number
91-04-129-20101-84041

Health conditions studied

1

Description of health condition studied
Generalized anxiety disorder
ICD-10 code
F41.1
ICD-10 code description
Anxiety that is generalized and persistent but not restricted to, or even strongly predominating in, any particular environmental circumstances (i.e. it is

2

Description of health condition studied
Depressive episode
ICD-10 code
F32
ICD-10 code description
In typical mild, moderate, or severe depressive episodes, the patient suffers from lowering of mood, reduction of energy, and decrease in activity. Capacity for enjoyment, interest, and concentration is reduced, and marked tiredness after even minimum eff

3

Description of health condition studied
Nonorganic insomnia
ICD-10 code
F51.0
ICD-10 code description
A condition of unsatisfactory quantity and/or quality of sleep, which persists for a considerable period of time, including difficulty falling asleep, difficulty staying asleep, or early final wakening

Primary outcomes

1

Description
Total body Antioxidant
Timepoint
In the first day of intervention and 20 days after
Method of measurement
Spectrophotometry techniques

2

Description
Anxiety
Timepoint
In the first day of intervention and 20 days after
Method of measurement
Ketel Questionnaire

3

Description
Depression
Timepoint

In the first day of intervention and 20 days after

Method of measurement

Standard Questionnaire of Beck

4

Description

Insomnia

Timepoint

In the first day of intervention and 20 days after

Method of measurement

Petersburg Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention: patients are drinking one glass of Melissa tea in the mornings and one glass of Melissa tea in the evenings for 20 days from the first day of intervention. This tea is teabag with the commercial name of Melis tea and is provided of using one teabag in 250 cc boiling water.

Category

Treatment - Drugs

2

Description

Control: Patients are drinking one glass of black tea in the mornings and one glass of black tea in the evenings for 20 days from the first day of intervention.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Motahari Burn Hospital

Full name of responsible person

Mohammad Javad Fatemi

Street address

Shahid Motahari Burn Hospital, Rashid Yasami Ave, Vali Asr Ave, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotouhi

Street address

Central Department of Tehran University of Medical Sciences, Keshavarz Bvld, Tehran

City

Tehran

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 of Tehran 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

Burn Research Center of Iran University of Medical sciences

Full name of responsible person

Mohammad Javad Fatemi

Position

Associate Professor of Plastic Reconstructive Surgery

Other areas of specialty/work

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

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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