

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Effects of *Melissa officinalis* extract on the level of anxiety in patients with leukemia: a randomized, double-blind, placebo-controlled clinical trial

Protocol summary

Summary

By the first leukemia recognition in patients between 16 and 60 year olds, The Beck Anxiety Inventory will be completed to assess the level of anxiety. 60 patients will be randomly and double blinded divided in to two groups. group one will take two capsules contained of 300 mg *Melissa officinalis* extract beside an SSRI each day for 8 weeks. Group two will take placebo and SSRI with the same protocol. at the end of week 2,4 and 8 Beck Anxiety Inventory will be completed again and level of anxiety will be assessed. Clinical findings will be analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017041926804N2**

Registration date: **2017-06-19, 1396/03/29**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-06-19, 1396/03/29

Registrant information

Name

Zahra Ayati

Name of organization / entity

Medical University of Mashhad

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2017-07-23, 1396/05/01

Expected recruitment end date

2020-01-01, 1398/10/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of *Melissa officinalis* extract on the level of anxiety in patients with leukemia: a randomized, double-blind, placebo-controlled clinical trial

Public title

Effect of Lemon balm on anxiety

Purpose

Treatment

Inclusion/Exclusion criteria

age between 18 to 60 years old; patients with new recognized leukemia; patients with anxiety; patients who take one SSRI beside the intervention; no pregnancy; no lactation; no other anti-anxiety herbal drug administration.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 70

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad University of Medical Sciences

Street address

Ahmad Abad Street, Mashhad

City

Mashhad

Postal code

91375-345

Approval date

2017-01-05, 1395/10/16

Ethics committee reference number

IR.MUMS.SP.1395.88

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F41.9

ICD-10 code description

Anxiety disorder, unspecified

Primary outcomes

1

Description

Beck anxiety Score

Timepoint

before intervention, 2,4 and 8 weeks after intervention

Method of measurement

Beck anxiety intervention

Secondary outcomes

1

Description

Treatment response

Timepoint

at the end of week 8 after intervention

Method of measurement

≥50% improvement in mean Beck Anxiety Inventory score

2

Description

Treatment response

Timepoint

at the end of week 8 after intervention

Method of measurement

difference of mean Beck anxiety score from baseline (treatment response is defined as ≥50% improvement)

Intervention groups

1

Description

Intervention group: Melissa officinalis (Lemon balm) extract, 300 mg cap, BID, 8 weeks

Category

Treatment - Drugs

2

Description

Control group:placebo, 300 mg cap, BID, 8 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghuaem Oncology Medicine Research Center

Full name of responsible person

Dr. Seyyedeh Tahereh Mohaddes

Street address

Mashhad. Ahmadabad street, Ghuaem hospital

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohsen. Tafaghodi

Street address

Mashhad. Daneshgah street. Ghoreishi building. F2.

City
Mashhad

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Mashhad 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

Department of traditional medicine , School of Pharmacy, Mashhad University of Medical Sciences, Mas

Full name of responsible person

Zahra Ayati

Position

PhD student

Other areas of specialty/work

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Assistant professor of Traditional Pharmacy

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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