

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

The effect of hydroalcoholic extract of *Nasturtium officinale* on quality of life in asthmatic patients

Protocol summary

Study aim

Determining the effect of hydro alcoholic extract of *Nasturtium officinale* on the quality of life in patients with asthma

Design

A randomized controlled clinical trial with parallel, double-blind, randomized, phase 2 group on 50 patients used the random allocation rule.

Settings and conduct

patients with asthma referred to Shahid Mofteh Hospital in Yasuj are randomly divided into two groups by random allocation method. patients in the intervention group (25 patients) receive *Nasturtium officinale* extract capsules and in the control group (25 patients) receive placebo (flour capsules) in the same form and amount. The treatment protocol in both groups in 500 mg capsules twice a day. Follow-up of patients is done every week during treatment and 8 weeks after the end of treatment. It should be noted that the patient and the researcher will not know about the assignment of groups and it is a double-blind study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: adult male/female (age 18-65 years); asthma diagnosis based on the Global Initiative for Asthma (GINA); asthma symptoms not fully controlled based on ACT (Asthma Control Test) score from 5 to 24; no severe asthma exacerbation in the last four weeks; Complete conscious satisfaction
Exclusion criteria: smoking history; pregnant women; taking any preparation containing NOE

Intervention groups

Intervention group: Capsules containing hydroalcoholic extract of *Nasturtium officinale*. Control group: Capsules containing flour

Main outcome variables

Mean quality of life score (by each dimension) of patients, mean score of sleep quality of patients with asthma, mean score of asthma control test (ACT) of patients, mean blood eosinophils of patients with asthma

and mean serum IgE of patients with asthma before and after intervention in the placebo group and the group receiving hydroalcoholic extract of watercress

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220506054749N1**

Registration date: **2022-06-08, 1401/03/18**

Registration timing: **registered_while_recruiting**

Last update: **2022-06-08, 1401/03/18**

Update count: **0**

Registration date

2022-06-08, 1401/03/18

Registrant information

Name

Ezat Zareie

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-22, 1401/03/01

Expected recruitment end date

2022-07-23, 1401/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title
The effect of hydroalcoholic extract of Nasturtium officinale on quality of life in asthmatic patients

Public title
The effect of hydroalcoholic extract of Nasturtium officinale on quality of life in asthmatic patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Both sexes age 18-65 years Asthma diagnosis based on the Global Initiative for Asthma (GINA) Asthma symptoms not fully controlled based on ACT (Asthma Control Test) score from 5 to 24 No severe asthma exacerbation in the last four weeks Complete conscious satisfaction
Exclusion criteria:
smoking history pregnant women taking any preparation containing NOE

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, we will use the Restricted randomization method of the randomization Random allocation rule method. For this purpose, first determine a total sample size, then randomly assign a set of them to the intervention group and the rest to the control group. 30 balls for the intervention group and 30 balls for the control group are placed in a lottery container and then the balls are randomly removed from the container without replacement and the created sequence is recorded.

Blinding (investigator's opinion)
Double blinded

Blinding description
Capsules are individually packed envelopes and have an identification number. Capsules and envelopes of Nasturtium officinale extract and placebo are offered in exactly the same appearance and packaging, which will blind the participants and the researcher.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Yasouj University of Medical Sciences

Street address

Motahari Boulevard

City

Yasuj

Province

Kohgiluyeh-va-Boyerahmad

Postal code

7591741417

Approval date

2020-11-24, 1399/09/04

Ethics committee reference number

IR.YUMS.REC.1399.157

Health conditions studied

1

Description of health condition studied

Asthma

ICD-10 code

J45

ICD-10 code description

Asthma

Primary outcomes

1

Description

Asthma Control Test score

Timepoint

Before intervention - 28 days after intervention

Method of measurement

ACT test questionnaire

Secondary outcomes

1

Description

Quality of life

Timepoint

Before intervention - 28 days after intervention

Method of measurement

Quality of Life Questionnaire (SF-12)

2

Description

Quality of sleep

Timepoint

Before intervention - 28 days after intervention

Method of measurement

Petersburg Sleep Quality Questionnaire (PSQI)

3

Description

Number of eosinophils

Timepoint

Before intervention - 28 days after intervention

Method of measurement

Cismax device

4

Description

Immunoglobulin E

Timepoint

Before intervention - 28 days after intervention

Method of measurement

Spectrophotometry

Intervention groups

1

Description

Intervention group: Watercress was collected from Shahniz (Margon) region of Kohgiluyeh and Boyer-Ahmad provinces in the summer of 1399. After collecting watercress, 100 grams of plant powder is soaked in 500 ml of ethanol and placed at room temperature for 48 hours. The extract is then filtered and the rest is extracted again with solvent after 24 hours and added to the original extract. The solvent is then evaporated at a temperature of 40 ° C by a rotary refrigerator and incubated at a temperature of 37 ° C to dry extract and stored in the refrigerator at a temperature of 4 ° C for further experiments. To the group of hydroalcoholic extract of watercress in the amount of 500 mg twice a day for 4 weeks. Blood samples and all questionnaires (including ACT test, quality of life and sleep disorders) are completed at the beginning and end of the study by research units. Blood samples are taken from the Clot and CBC tubes. To measure the number of blood eosinophils, a CBC test is performed with a Cismax device. The serum sample is also elucidated and stored at minus -70 ° C. IgE levels are then measured.

Category

Treatment - Drugs

2

Description

Control group: Flour and capsules were prepared and placed in 500 mg capsules in jars of the same shape and size as the main medicine and packaged (of course in the university without my presence) and the patient was

explained in person that twice a day. Consume for 28 days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Mofattah Clinic, Yasuj

Full name of responsible person

Reza Abbasi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Yasouj 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
Yasouj University of Medical Sciences
Full name of responsible person
Dr Reza Abbasi
Position
Professor
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

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

Undecided - It is not yet known if there will be 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