

# 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)

##### Phone

+98 71 3730 2150

##### Email address

zaree.e@yums.ac.ir

##### 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

##### **Street address**

Shahid Motahari Boulevard

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## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Yasouj University of Medical Sciences

##### **Full name of responsible person**

Amirhossein Doustimotlagh

##### **Street address**

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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  
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Dr Reza Abbasi  
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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