

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Feb 2026

### Effect of Eucalyptus oil inhalation on pain and quality of life in patients with rheumatoid arthritis

#### Protocol summary

##### Study aim

The aim of this study was to determine the effect of inhalation of eucalyptus oil on the severity of pain and quality of life in patients with rheumatoid arthritis.

##### Design

The present study is a randomized clinical trial with two parallel groups which is done on 70 patients.

##### Settings and conduct

This study will be performed on 70 patients with rheumatoid arthritis admitted to the hospital. In the intervention group, 1 ml of Eucalyptus oil will be inhaled for 5 minutes. In the control group, distilled water will be used. The severity of pain and quality of life in patients will be evaluated using VAS and SF-12 questionnaires within a month.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Having at least one year of the definitive diagnosis of articular rheumatism, Absence of history of allergy, allergic rhinitis, asthma, and chronic pulmonary disease, No use of aromatherapy in the past month, Having complete and informed consent to participate in the study, Confirmed diagnosis of rheumatoid arthritis by the physician, Age between 18 and 60 years old Exclusion criteria: Allergy to eucalyptus, Changing the disease process, death, The patient migrates to another place

##### Intervention groups

In the intervention group: 1 ml of eucalyptus oil is poured on a 4 × 2 inch gas and placed at a distance of 30 cm from the nose of the patients and is inhaled for 5 minutes. The patient's pain will be evaluated using the VAS. In the control group: Except for routine medication and care, no special action will be taken.

##### Main outcome variables

pain; quality of life

#### General information

##### Reason for update

In the inclusion criteria section, instead of patients with rheumatoid arthritis, patients with MS are written.

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160110025929N15**

Registration date: **2018-10-07, 1397/07/15**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-10-19, 1400/07/27**

Update count: **1**

##### Registration date

2018-10-07, 1397/07/15

##### Registrant information

##### Name

Mehdi Molavi Vardanjani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 3422 5056

##### Email address

m.molavi@umsha.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-09-23, 1397/07/01

##### Expected recruitment end date

2019-09-23, 1398/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of Eucalyptus oil inhalation on pain and quality of

life in patients with rheumatoid arthritis

## Public title

Effect of inhalation of eucalyptus oil on pain and quality of life

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Age between 18 and 60 years old  
Confirmed diagnosis of rheumatoid arthritis by the physician  
Having complete and informed consent to participate in the study  
No use of aromatherapy in the past month  
Absence of history of allergy, allergic rhinitis, asthma, and chronic pulmonary disease  
Having at least one year of the definitive diagnosis of articular rheumatism

### Exclusion criteria:

Allergy to eucalyptus  
Changing the disease process  
Death  
The patient migrates to another place

## Age

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

## Gender

Both

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: **70**

## Randomization (investigator's opinion)

Randomized

## Randomization description

70 patients will be selected through available sampling. Then the patients will be assigned to the groups using block randomization method.

## 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 Hamadan University of Medical Sciences

##### Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Street

##### City

Hamadan

##### Province

Hamadan

## Postal code

38698-65178

## Approval date

2018-09-01, 1397/06/10

## Ethics committee reference number

IR.UMSHA.REC.1397.408

## Health conditions studied

### 1

#### Description of health condition studied

Rheumatoid Arthritis

#### ICD-10 code

M05.10

#### ICD-10 code description

Rheumatoid lung disease with rheumatoid arthritis of unspecified site

## Primary outcomes

### 1

#### Description

Quality of life

#### Timepoint

Before and after intervention

#### Method of measurement

SF-12 Questionnaire

### 2

#### Description

Pain

#### Timepoint

Before and after intervention

#### Method of measurement

Visual Analog Scale

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: 1 ml of eucalyptus oil is poured on a 4 × 2 inch cloth and placed at a distance of 30 cm from the nose of the patients and inhaled for 5 minutes.

#### Category

N/A

### 2

#### Description

Control group: 1 ml of distilled water is poured on a 4 × 2 inch cloth and placed at a distance of 30 cm from the nose of the patients and inhaled for 5 minutes.

#### Category

N/A

**Type of organization providing the funding**  
Academic

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Beheshti hospital

**Full name of responsible person**

Arezoo Karampourian

**Street address**

Beheshti hospital, Beheshti Street

**City**

Hamedan

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+98 81 3838 0535

**Email**

a.karampourian@umsha.ac.ir

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Saeed Bashirian

**Street address**

Hamadan University of Medical Sciences, Shahid Fahmideh Street

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**Grant name**

**Grant code / Reference number**

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

No

**Title of funding source**

Deputy of Research and Technology

**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**

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Arezoo Karampourian

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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## Person responsible for scientific inquiries

### Contact

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**Full name of responsible person**

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**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Zahra Kord

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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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