Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the Effect of Foot Reflexology and Foot Rub Olive Oil on Asthma Control

Protocol summary

Summary

This study is a randomized controlled clinical trial. It will be done with purpose of comparing the effects of foot reflexology and foot rub olive oil on asthma control. The project will be implemented after receiving referral letter from the vice chancellor for research of Tabriz university of medical sciences and obtain permission from the ethics committee of Tabriz university of medical sciences and coordination with the officials of specialized and professional pulmonary clinic of Imam Khomeini hospital in Ardabil for patients admitted to this place. The study comprised two intervention groups (a group of foot reflexology and other foot rub olive oil) and a control group. The number of participants in the study determined at least 40 patients by means of this formula: n> sd2 (zα + zβ)2/d2 , (51 patients were selected). It is noteworthy that the standard deviation of the difference between the two groups of studies with variable FEV1, 4.5 is obtained. Participants will be selected through available. The samples will elected from patients who referred to a physician in specialized and professional pulmonary clinic of Imam Khomeini hospital and his medical office in Ardabil. All the adult women should be over 12 years with a diagnosis of asthma. In the first session for each groups of this study the purpose of the study and how to carry out it will be explained and after completion the consent form, the Asthma Control Questionnaire (containing 6 questions, seven points in each question that evaluate asthma control) will be completed By the participants and supervised by a trained researcher assist to avoid bias while completing the questionnaire. All three groups will continue previous asthma medications as directed by their doctors as the routine. Interventions will be done for 10 sessions, twice per week for 15 minutes on each foot by a trained researcher. Interventions will be done in a private room of the clinic. At the end of 10 session intervention and one day after that the questionnaires will be completed again. The implement of Interventions and completion of questionnaires in all three groups will be conducted in parallel and simultaneously. To avoid interference with other group participants, participants in each group will receive the intervention in separate days. The data collected will be compared with each other and asthma control variable will be compared at the beginning and end of the study and between three groups and with the aid of the SPSS 13 will analyze. 1 - Objectives: Comparison of the effects of foot reflexology and foot rub olive oil on asthma control. Dedicated objectives: Determine and comparison the adequacy of asthma control in foot reflexology group before and after intervention؛ Determine and comparison the adequacy of asthma control in foot rub olive oil group before and after intervention؛ Determine and comparison the adequacy of asthma control in control group at the beginning and end of the study؛ comparison of the adequacy variations of asthma control in the three groups at the beginning and end of the study. 2 - Design: randomized controlled clinical trial. 3 - Setting and conduct: After completion of consent form the Asthma Control Questionnaire will be completed By the participants. All three groups will continue previous asthma medications as directed by their doctors by routine. Interventions will be done for 10 sessions, twice per week for 15 minutes on each foot by a trained researcher. At the end of 10 session intervention and one day after that the questionnaires will be completed again. Intervention implementation and completion of questionnaires in all three groups will be conducted in parallel and simultaneously. 4 - Participants including major eligibility criteria: All the adult women should be over 12 years with a diagnosis of asthma. Inclusion criteria: Women should be over 12 years old؛ Suffering from asthma. Exclusion criteria: Be pregnant؛ Having injury or infection in foot؛ Suffering from cancer or any other blood infections؛ Taking psychiatric drugs؛ Have any fracture in the foot؛ Have leg edema؛ Have DVT؛ Will be hospitalized during the study؛ Suffering from diabetic neuropathy؛ Using of other asthma treatments other than drugs prescribed by doctors. 5 - Intervention: Foot reflexology؛ Foot rub olive

oil؛ Control(without intervention). 6 -Main outcome measures variables: Asthma control.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012122011825N1**
Registration date: **2013-05-27, 1392/03/06**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-05-27, 1392/03/06

Registrant information

Name
Seemin Dashti

Name of organization / entity
Medical Sciences University Of Tabriz, Faculty Of Nursing And Midwifery of Tabriz

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research,Tabriz University of Medical Sciences

Expected recruitment start date

2013-04-29, 1392/02/09

Expected recruitment end date

2013-05-14, 1392/02/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effect of Foot Reflexology and Foot Rub Olive Oil on Asthma Control

Public title

Comparison of the Effect of Foot Massage and Foot Rub Olive Oil on Asthma Control

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Women should have over 12 years old؛ Suffering from asthma. Exclusion criteria: Be pregnant؛ Having injury or infection in foot ؛ Suffering from cancer or any other blood infections؛ Taking psychiatric drugs؛ Have any fracture in the foot؛ Have leg edema (Increase in diameter of the ankle or forearm with or without pitting)؛ Have DVT (warmth, swelling, edema and pain in leg)؛ Be hospitalized during the study؛ Suffering from diabetic neuropathy (Eliminating the achilles reflex, Decreased pain and temperature sensation in patients with diabetes)؛ Using of other asthma treatments except drugs that prescribed by doctors.

Age

From **12 years** old to **100 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **51**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Tabriz University Of Medical Sciences

Street address
Faculty of Nursing & Midwifery, Shariety South Street,Tabriz, Iran

City
Tabriz

Postal code

Approval date

2013-04-29, 1392/02/09

Ethics committee reference number

1922

Health conditions studied

1

Description of health condition studied

Asthma

ICD-10 code

J45.8

ICD-10 code description

Mixed asthma

Primary outcomes

1

Description
Asthma Control
Timepoint
Before the intervention, A day after intervention
Method of measurement
Asthma Control Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Foot reflexology: A special massage for the bottom, metatarsus and sides of the foot. It will be done for 10 sessions, twice per week for 15 minutes on each foot by a trained researcher.
Category
Other

2

Description
Olive oil rubbing: Rub olive oil on the metatarsus, sides and bottom of foot. It will be done for 10 sessions, twice per week for 15 minutes on each foot by a trained researcher.
Category
Other

3

Description
Control: Without intervention
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Specialty Pulmonary Clinic of Imam Khomeini Hospital in Ardabil; Dr Muhammad Mirzaaqhazadeh Medical
Full name of responsible person
Seemin Dashti
Street address
Imam Khomeini Hospital, Bagheri Jeddi street, Ardabil; Navid Practitioners Building, Tavar alley, Sarcheshmeh street, Ardabil
City
Ardabil

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research,Tabriz University of Medical Sciences
Full name of responsible person
Dr. Seyed Kazem Shakouri (Vice chancellor for research,Tabriz University of Medical Sciences)
Street address
Deputy of Tabriz University of Medical Sciences, Golgasht Street, Azadi Street, Tabriz
City
Tabriz
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,Tabriz 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

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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