Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effect of Anthurium Fruit Extract on Arthralgia Pain in Patients with Rheumatoid Arthritis Referring to the Clinic of the Iranian Rheumatism Center

Protocol summary

Study aim
the aim of this study was to evaluate the effect of Elaeagnus angustifolia extract on reducing pain in patients with rheumatoid arthritis.

Design
A double blind clinical trial with a case group and a control group that Elaeagnus angustifolia extract pill and placebo were administered to the case and control group, respectively. Sampling method in this randomized study was available sampling .

Settings and conduct
In this research, patients who referred to rheumatology clinics of the Iranian Rheumatism Center who were eligible to enter the study were randomly allocated in two groups of case and control. The case group was anesthetized Elaeagnus angustifolia pill and control group received placebo. This study was double-blind.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1. Have a diagnosis of rheumatoid arthritis from a doctor at least 6 months ago. People aged 25 to 65 years 2. In painful areas and joints, there were no injuries, open wounds and fractures. 3. Not using other therapies such as hydrotherapy, thermal therapy, acupuncture Exclusion criteria: severe pain, consuming medication or intra-articular injection.

Intervention groups
Giving the Elaeagnus angustifolia pill to the case group and giving the placebo to the control group

Main outcome variables
Pain severity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180421039375N1**
Registration date: **2018-09-24, 1397/07/02**
Registration timing: **retrospective**

Last update: **2018-09-24, 1397/07/02**
Update count: **0**

Registration date
2018-09-24, 1397/07/02

Registrant information

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2016-03-20, 1395/01/01

Expected recruitment end date
2017-03-21, 1396/01/01

Actual recruitment start date
2016-04-03, 1395/01/15

Actual recruitment end date
2017-03-21, 1396/01/01

Trial completion date
2017-03-21, 1396/01/01

Scientific title
The Effect of Anthurium Fruit Extract on Arthralgia Pain in Patients with Rheumatoid Arthritis Referring to the Clinic of the Iranian Rheumatism Center

Public title

The Effect of Anthurium Fruit Extract on Arthralgia Pain

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Having a diagnosis of rheumatoid arthritis by a doctor at least 6 months ago, Medical records referring to rheumatology clinics of Tehran rheumatology center of Iran. People aged 25 to 65 years There was no injury, open wounds and fractures in painful areas and joints, Willingness to participatein research. Not using other therapies such as hydrotherapy, thermotherapy, acupuncture

Exclusion criteria:

Unwillingness to continue cooperation in research. Patients who did not have good cooperation, did not take medication properly or did not have regular follow-up. Due to much pain, consuming medication or intra-articular injection.

Age

From **36 years** old to **55 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **100**

Actual sample size reached: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, 96 patients were selected randomly from patients referred to rheumatology clinics of Iran Rheumatology Center and divided into two groups of case and control. In order to collect the data, eligible patients referred to the rheumatology clinic of the Iranian Rheumatology Center who were willing to participate in the study were randomly and double blind divided into two groups of patients receiving the Anthurium fruit extract and placebo in every other day. These drugs were packaged in two packets of 60 (Package A, Pack B) and were given to every other patient.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, 4 groups of patients, clinical caregivers, outcome evaluators, and data analyzers were kept blind. None of these quotes knew which pills were a placebo and which are the main drugs (Anthurium Fruit Extract).

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Islamic University of Medical Sciences

Street address

Khaghani St, Shariati Ave

City

Tehran

Province

Tehran

Postal code

19395/1495

Approval date

2015-03-22, 1394/01/02

Ethics committee reference number

Ir.iau.tmu.rec.1394.17

Health conditions studied

1

Description of health condition studied

rheumatoid arthritis

ICD-10 code

M05

ICD-10 code description

Rheumatoid arthritis with rheumatoid factor

Primary outcomes

1

Description

Severe pain in joints

Timepoint

Before the intervention and 30 days after taking the medication

Method of measurement

questionnaire

Secondary outcomes

1

Description

Quality of life Score

Timepoint

Quality of Life / Before the start of the study and one month after the start of the study

Method of measurement

Questionnaire with 24 questions

Intervention groups

1

Description
The intervention group received a 500 mg capsule (A package) every 12 hours for 30 days.
Category
Treatment - Drugs

2

Description
Control group: The placebo group received a 500 mg capsule (B package) for 30 days every 12 hours.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Clinic of the Iranian Rheumatism Center
Full name of responsible person
Dr. Mohammad Eslami Vaghar
Street address
No. 70 and79, Khosravi Alley, above the gas station, North Kargar Street,Tehran
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Web page address
http://www.rcr.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Dr. Farshad Hashemian
Street address
Tehran University of Medical Sciences, Khaghani St., Shariati St.
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Phone
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Email
iautmu@iautmu.ac.ir
Web page address
http://iautmu.ac.ir/index.asp
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Islamic Azad University, Tehran Medical Sciences Branch, Vice Chancellor for Research and Technology
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
Islamic Azad University
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Hamid Zaferani Arani
Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data can be shared after unidentifiable people. Effect of Oral anesthetic Elaeagnus angustifolia extract on pain score in patients with rheumatoid arthritis
When the data will become available and for how long
After publishing its article
To whom data/document is available
All researchers - have no limits
Under which criteria data/document could be used
Provided that the researcher wants to do the same
From where data/document is obtainable
Person responsible for research
What processes are involved for a request to access data/document
Email to Person responsible - Checked by the responsible - Providing information
Comments