Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of Ajwain cream in patients with neuropathic foot, a double blind randomized controlled clinical trial

Protocol summary

Summary

Neuropathic pain is a chronic and progressive pain which is associated with the Neuropathic pain is a chronic disorder associated with the impairment and damage of nervous system. Overall 1% of the human population around the world and totally 2-8% of adolescents suffer from this disorder. In the management, various medications and interventions are applied. But according to the nature of the disorder which is commonly chronic, patient has to handle long period of management. Therefore, topical medication may have more advantages compared to the systemic drugs. Accordingly, current study aimed to evaluate the effectiveness Ajwain cream in neuropathic foot burn via a double-blind randomized placebo-controlled clinical trial. Seed oil of Ajwain is considered as a potent medicament for neurological disorders in Traditional Persian Medicine. Simple randomization was done for a sample of 92 patients as two groups (placebo and Ajwain). Patients were introduced to either placebo or Ajwain group. Inclusion criteria: nonpregnant adults with neuropathic pain diagnosis; diabetic neuropathy; postsurgical/posttraumatic neuropathic pain; pain persisted for 6 months or longer and presence of dynamic allodynia in the site of pain. Exclusion criteria: patients suffering from another type of pain; psychiatric disorder requires special intervention; history of hypersensitivity or allergic reactions to herbal medicament; pregnant volunteer. Intervention included Ajwain placebo group. Primary outcomes were considered as feet burn, allodynia, paraesthesia and numbness in patient’s feet while feet burn is the most important parameter. Analysis was based on using the Visual Analog Scale on a 0 to 10 Cm scale. Patients were asked to fulfill the questionnaire before starting the new drug, in the middle of the procedure and ending point (day30).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201201248815N1**
Registration date: **2012-06-12, 1391/03/23**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-06-12, 1391/03/23

Registrant information

Name
Mohammad Mehdi Zarshenas
Name of organization / entity
Shiraz University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2012-04-21, 1391/02/02

Expected recruitment end date

2012-10-23, 1391/08/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of Ajwain cream in patients with neuropathic foot, a double blind randomized controlled clinical trial

Public title
Evaluation of Ajwain cream in patients with neuropathic foot

Purpose
Treatment

Inclusion/Exclusion criteria
The inclusion criteria for this study were encompassing nonpregnant adults with neuropathic pain diagnosis; diabetic neuropathy; postsurgical/posttraumatic neuropathic pain; moderate to severe pain persisted for 6 months or longer and presence of dynamic tactile allodynia or hyperalgesia in the site of pain in patients with normal cognitive and cooperation. In contrast, patients suffering from another type as severe as the above pain; a major depression or psychiatric disorder requiring special intervention; patients with history of hypersensitivity or allergic reactions to the essential oils or herbal medicament; children and pregnant volunteers and anybody who does not have the ability to participate were excluded.

Age
No age limit

Gender
Male

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **92**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
The Ethics committee of Shiraz University of Medical Sciences

Street address
Shiraz University of Medical Sciences

City
Zand Street

Postal code

Approval date
2011-10-09, 1390/07/17

Ethics committee reference number
CT 90 5802

Health conditions studied

1

Description of health condition studied
Neuropathic pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Change or any declines in foot burn in neuropathic foot

Timepoint
The first day of addmision, middle of the trial (the day 15) and the end (the day 30)

Method of measurement
visual analoge scale (from 0 to 10)

Secondary outcomes

empty

Intervention groups

1

Description
A double-blind randomized placebo-controlled clinical trial Group of Ajwain cream: Cream is an oil in water semisolid formulation which is made up of almond oil (10%), Beeswax (5%), Vaseline (10%), Tween 80 (1%), and essential oil of Carum copticum (10%). Patients are introduced to apply 5cm of cream of cream on the affected area of their feet twice a day for 30 days.

Category
Treatment - Drugs

2

Description
double-blind randomized placebo-controlled clinical trial Group of placebo cream Placebo cream is an oil in water semisolid formulation which is made up of almond oil (20%), Beeswax (5%), Vaseline (10%) and Tween 80 (1%). Patients are introduced to apply 5cm of cream of cream on the affected area of their feet twice a day for 30 days

Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Faculty of Pharmacy, Shiraz University of Medical Sciences
Full name of responsible person
Mohammad M. Zarshenas
Street address
City
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2

Recruitment center
Name of recruitment center
Imam Reza Cinic
Full name of responsible person
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Shiraz University of Medical Sciences
Full name of responsible person
Dr Gholamreza Hatam
Street address
Vice Chancellor for Research, 7th floor, Shiraz Univercity of Medical Sciences, Zand st
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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
Vice Chancellor for Research, Shiraz 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

Contact
Name of organization / entity
Faculty of Pharmacy, Shiraz University of Medical Sciences
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Position
PhD candidate
Other areas of specialty/work
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Person responsible for updating data

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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