Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparsion of topical amitriptyline and topical capsaicn in pain reduction of painful diabetic neuropathy of type2 diabetic patients

Protocol summary

Summary

This study is double blind randomized clinical trial that is planned for the comparison of the effects of topical capsaicin and topical amitriptyline in pain reduction of patients with painful diabetic neuropathy. The study population consists of type two diabetic patients. Patients with painful diabetic neuropathy with visual analogue scale equal and grater than four will be included. Patients with hepatic or renal failure, use of other drugs for pain reduction and HA1C≥9 will be excluded. After signing the informed consent, the eligible patients (100 patients) will be assigned randomly into two different groups: Capsaicin and amitriptyline. Patients in capsaicin group will receive 0.75% capsaicine cream three times a day on the feet. Patients in amitriptyline group will receive 2% amitriptyline cream three times a day on the feet. The primary outcome is pain reduction and will be assed by visual analogue scale at the end of each month up to three month. At the end of the study mean pain reduction will be compared in two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201209238308N2**
Registration date: **2012-09-28, 1391/07/07**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2012-09-28, 1391/07/07

Registrant information

Name

Javad Kiani

Name of organization / entity

College of Medical Sciences, Hamedan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 81 1838 0155

Email address

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Recruitment status

Recruitment complete

Funding source

Hamedan University of Medical Sciences

Expected recruitment start date

2012-11-01, 1391/08/11

Expected recruitment end date

2013-05-01, 1392/02/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparsion of topical amitriptyline and topical capsaicn in pain reduction of painful diabetic neuropathy of type2 diabetic patients

Public title

Comparsion of amitriptyline and capsaicn in painful diabetic neuropathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Type two diabetic patients with Painfull diabetic neuropathy Exclusion criteria: Duration of diabetes less than one year; Age <30 or >70 years; VAS<4; Type one diabetes; Other causes of neuropathy other than diabetes; Opiom or alcohol users; Use of other

drugs for pain reduction; Hepatic or renal failure; HA1C≥9; Pregnancy or lactation; Ulcer or infection of foot; Hypersensitivity to pepper

Age
From **30 years** old to **70 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics committee

Street address
Hamedan University of Medical Scinces, Shahid fahmide street

City
Hamedan

Postal code

Approval date
2012-06-30, 1391/04/10

Ethics committee reference number
D/P/16/35/9/1282

Health conditions studied

1

Description of health condition studied
Painfull Diabetic Polyneuropathy

ICD-10 code
G63.2

ICD-10 code description
Diabetic polyneuropathy

Primary outcomes

1

Description
Pain intensity

Timepoint
At baseline, one, two and three month later

Method of measurement
Visual Analouge Scale

Secondary outcomes

1

Description
Any adverse effect

Timepoint
one, two and three month later

Method of measurement
Questioner

Intervention groups

1

Description
Intervention 1 : Capsaicin cream 0.75% three times a day on the feet (nearly 1 gram each time) for three month.

Category
Treatment - Drugs

2

Description
Intervention 2 : amitriptyline cream 2% three times a day on the feet (nearly 1 gram each time) for three month.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Emam Khomeini Clinic

Full name of responsible person

Street address

City
Hamedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice-chancellor of Research and Technology,Hamedan university of Medical Sciences

Full name of responsible person
Heydar Tavilani

Street address

Shahid Fahmideh Street, Hamedan university of Medical Sciences

City

Hamedan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice-chancellor of Research and Technology,Hamedan 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

College of Medical Sciences, Hamedan University of Medical Sciences

Full name of responsible person

Javad Kiani

Position

Assistant Proffesor of Endocrinology

Other areas of specialty/work

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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