

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 2026

### Comparision 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 $\geq$ 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)

##### Phone

+98 81 1838 0155

##### Email address

javadkiani@umsha.ac.ir

##### 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

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

##### Public title

Comparision 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 Sciences, 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 Analogue 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 Professor of Endocrinology

**Other areas of specialty/work**

**Street address**

Shahid Beheshti Hospital, Eram Blv., Hamedan

**City**

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+98 81 1838 0704

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**Email**

javadkiani@umsha.ac.ir

**Web page address**

**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*