

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The effect of transdermal nitroglycerin on pain control of painful peripheral diabetic neuropathy: A crossover, double-blinded and placebo-controlled study

Protocol summary

Summary

In this crossover study 30 patients with painful peripheral diabetic neuropathy over 18 years of age will randomly allocate to two groups of drug and placebo which will receive nitroglycerin plasters and placebo patches for 4 weeks. Then they will a 3 week course of washout period and thereafter they will be treated by the compound of the other group (drug or placebo) for another 4 week period. Pain intensity as the primary outcome of the study will be assessed by NRS score. Secondary outcomes and their measurement tools will be: patient's physical functioning (SF-36 Health Survey and BPI), psychological and emotional status of the patients (BDI), the sense of well-being and satisfaction (PGIC), frequency and severity of treatment related side effects. These data will compared in two phases of treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201308223213N1**
Registration date: **2013-10-03, 1392/07/11**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-10-03, 1392/07/11

Registrant information

Name

Arash Farbood

Name of organization / entity

Shiraz University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Research budget of Endocrinology and Metabolism
Research Institute, Tehran University of Medical Sciences

Expected recruitment start date

2012-04-24, 1391/02/05

Expected recruitment end date

2013-03-02, 1391/12/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of transdermal nitroglycerin on pain control of painful peripheral diabetic neuropathy: A crossover, double-blinded and placebo-controlled study

Public title

Effect of transcutaneous nitroglycerin on painful diabetic neuropathy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: more than 18 years of age ; history of type 1 or 2 diabetes ; Hb A1c level below 8.5% ; symptoms of symmetrical peripheral neuropathy in distal lower extremities ; pain severity more than 4 of 10 in NRS scale at the beginning of the study ; the patients' willingness, knowledge and ability for participation
Exclusion criteria: patients with ischemic heart and lower

extremity peripheral arterial disease ; patients with diabetic foot ulcers ; patients with history of peripheral neuropathies from other causes (e.g. hypothyroidism, vitamin B12 or folate deficiency, sarcoidosis and alcoholism) ; patients who receive vasodilating compounds like nitroglycerine and sildenafil

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 30

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Diabetes Research Center/Institute of Endocrinology and Metabolism/Tehran University of Medical Scie

Street address

Diabetes Research Center, 5th floor, Diabetes and Metabolic Disease clinic, next to the Tehran Heart Center Emergency Department, Heyaat Alley, Western 17th Shahrivar Avenue, Northren Kargar Street, Amirabad

City

Tehran

Postal code

Approval date

2011-08-27, 1390/06/05

Ethics committee reference number

00185

Health conditions studied

1

Description of health condition studied

Diabetic polyneuropathy

ICD-10 code

G63.2

ICD-10 code description

Diabetic polyneuropathy

Primary outcomes

1

Description

Pain intensity

Timepoint

2 times weekly

Method of measurement

Numerical Rating Scale

Secondary outcomes

1

Description

Patient`s physical functioning

Timepoint

Once after each phase of treatment (with drug and placebo)

Method of measurement

SF-36 and BPI questionnaires

2

Description

Psychological and emotional status of the patients

Timepoint

Once after each phase of treatment (with drug and placebo)

Method of measurement

BDI

3

Description

Patient`s global satisfaction and sense of well-being

Timepoint

Once after each phase of treatment (with drug and placebo)

Method of measurement

PGIC questionnaire

4

Description

Frequency and severity of treatment related side effects

Timepoint

Once a week during the treatment phases

Method of measurement

Frequency and severity measurement

Intervention groups

1

Description

In the study group the patients will be asked to apply 0.2

mg/hr transcutaneous nitroglycerin plasters (Nitro-Dur, Schering-Plough Pty Ltd., Australia) for 12 hours daily and for 4 weeks.

Category

Treatment - Drugs

2

Description

In the placebo group the patients will be asked to apply transcutaneous placebo plasters for 12 hours daily and for 4 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes & Metabolic Diseases Clinic/ Endocrinology & Metabolism Research Institute/Tehran University

Full name of responsible person

Ghazaleh Ebrahimi Khaneqah, MD

Street address

Next to the Tehran Heart Center Emergency Department, Shahrivar Alley, Northren Kargar Avenue

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Diabetes Research Center/Institute of Endocrinology and Metabolism/Tehran University of Medical Scie

Full name of responsible person

Ramin Heshmat

Street address

Ramin Heshmat

City

Tehran

Grant name

Grant code / Reference number

669

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

Yes

Title of funding source

Diabetes Research Center/Institute of Endocrinology and Metabolism/Tehran University of Medical Scie

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

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Full name of responsible person

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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