Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 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 compund 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

Country

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 begining 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 Istitute/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

City

Tehran

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

Shiraz University of Medical Sciences

Full name of responsible person

Arash Farbood

Position

Anesthesiologist/Assistant professor

Other areas of specialty/work

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Assistant professor/Anesthesiologist/Pain fellowship

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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