Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of analgesic effects of baclofen 2% cream in the treatment of peripheral diabetic neuropathy:A Randomized, placebo control, double blind clinical trial

Protocol summary

Summary

To evaluate topical analgesic effect of baclofen, this randomized, double-blind, Placebo control, clinical trial is designed. Patients refer to diabetes clinic with neuropathic pain are chosen and randomized to receive one of two intervention. Patients with moderate to severe peripheral neuropathy enrolled to the study. Patients with a history of peripheral neuropathy for other reason than diabetes, or treated with oral medicines with analgesic effect on neuropathy (anticonvulsants, tricyclic antidepressants) and, patients with hypersensitivity to baclofen are excluded. The total sample size is 80 people, forty patients in baclofen group and 40 patients in the placebo group. For this purpose, baclofen cream 2% is prepared, chemical and physical stability is evaluated in different temperature. Microbial limit test is also performed, same as the United States pharmacopeia method. In addition to taking oral amitriptyline, patients applied baclofen or placebo cream twice daily, for two weeks. At the end, patients reevaluated for severity of neuropathy. Pain intensity is recorded on first and 14th days after intervention, using Visual analog scale. The lowest grade of pain is considered 0 and the highest grade is 10.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201609053014N13**
Registration date: **2016-12-19, 1395/09/29**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-12-19, 1395/09/29

Registrant information

Name
Shahram Ala
Name of organization / entity
Mazandaran University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 15 1354 3083
Email address
sala@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor of Research, Mazandaran University of Medical Science

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2017-09-23, 1396/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of analgesic effects of baclofen 2% cream in the treatment of peripheral diabetic neuropathy:A Randomized, placebo control, double blind clinical trial

Public title

Evaluation of baclofen cream in the treatment of diabetic neuropathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: all patient with intermediate and severe peripheral neuropathy acording to United Kingdom screening test Exclusion criteria: patient with history of peripheral neuropathy not becouse of diabetes; taking oral medicine with analgesic effects on neuropathic pain (anticonvulsants, tricyclic acid antidepressants); patient with hypersensivity history to baclofen.

Age
From **18 years** old to **90 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
Randomization is done using random number table. We give a code number to each patient that shows the group each patient is allocated to. The list of patients and their code numbers is kept secret until the end of the trial. In this way neither the patient nor the researchers know whether it is drug or placebo.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Mazandaran University Medical Sciences

Street address
Moalem Sq.

City
Sari

Postal code

Approval date
2016-09-20, 1395/06/30

Ethics committee reference number
IR.Mazums.Rec.95-2371

Health conditions studied

1

Description of health condition studied
Diabetic neuropathy

ICD-10 code
G63.2

ICD-10 code description
Diabetic polyneuropathy

Primary outcomes

1

Description
Pain intensity

Timepoint
Before intervention;14 days after intervention

Method of measurement
Visual analog scale

Secondary outcomes

1

Description
Side effects

Timepoint
After intervention

Method of measurement
Questionnarie

Intervention groups

1

Description
Intervention: Cream baclofen 2%, twice daily for 14 days

Category
Treatment - Drugs

2

Description
Control: Cream without active ingredient, twice daily for 14 days

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Diabetes clinic, Mazandaran University of Medical Science

Full name of responsible person
Dr. Shahram Ala

Street address

City
Ramsar

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor Of Rasearch, Mazandaran University of Medical Sciences

Full name of responsible person
Dr Ahmadali Enayatifar

Street address
Payambar Azam University Complex, Mazandaran University of Medical Sciences, Faculty of Pharmacy, Km 18 Khazar Abad Road

City
Sari

Grant name

Grant code / Reference number

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

Title of funding source
Vice Chancellor Of Rasearch, Mazandaran 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
Mazandaran University Of Medical Science, Faculty of Pharmacy

Full name of responsible person
Dr Shahram Ala

Position
Clinical Pharmacy Specialist, Associated Professor

Other areas of specialty/work

Street address
Payambar Azam University Complex, Mazandaran University of Medical Sciences, Faculty of Pharmacy, Km 18 Khazar Abad Road

City
Sari

Postal code

Phone
+98 11 3354 3082

Fax

Email
sala@mazums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mazandaran University of Medical Science, Facualty of Pharmacy

Full name of responsible person
Dr Shahram Ala

Position
Clinical Pharmacy Specialist, Associated Professor

Other areas of specialty/work

Street address
Payambar Azam University Complex, Mazandaran University of Medical Sciences, Faculty of Pharmacy, Km 18 Khazar Abad Road

City
Sari

Postal code

Phone
+98 11 3354 3082

Fax

Email
sala@mazums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Mazandaran University of Medical Science, Faculty of Pharmacy

Full name of responsible person
Mahila Monajati

Position
Resident of Clinical Pharmacy

Other areas of specialty/work

Street address
Payambar Azam University Complex, 20 km khazar abad Road

City
Sari

Postal code

Phone
+98 11 3354 3814

Fax

Email
mahilamonajati@gmail.com

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