

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effectiveness of noscapine capsules in patients with Buerger's disease

Protocol summary

Study aim

Evaluation of noscapine on pain relief and symptoms of buerger disease

Design

The study of a single, non-randomized, phase 2, two-way informed clinical trial is performed on 15 patients with Buerger's disease.

Settings and conduct

Buerger's patients referred to the office of Dr Taheri, a specialist in vascular surgery, who receive noscapine 30 mg twice a day for 60 days. The study of a single, non-randomized, phase 2, two-way informed clinical trial is performed on 15 patients with Buerger's disease.

Participants/Inclusion and exclusion criteria

-Inclusion criteria: Age less than 50 years; Smoking history; Upper limb involvement or migratory thrombophlebitis; Infra-popliteal vascular involvement -
Exclusion criteria: No burning pain and paresthesia at the time of referral; Allergy symptoms and drug allergies; More than 2-fold increase in the upper limit of liver enzymes; More than 2-fold increase in the upper limit of renal function indices; lake of consent to continued the intervention

Intervention groups

administration of Noscadin capsules twice a day for 60 days

Main outcome variables

Measurement of VAS of pain criteria before and after the treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180103038199N5**

Registration date: **2021-05-12, 1400/02/22**

Registration timing: **prospective**

Last update: **2021-05-12, 1400/02/22**

Update count: **0**

Registration date

2021-05-12, 1400/02/22

Registrant information

Name

Vahid Reza Askari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3800 2264

Email address

askariv941@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-22, 1400/04/01

Expected recruitment end date

2023-03-20, 1401/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of noscapine capsules in patients with Buerger's disease

Public title

Study of noscapine in Buerger's disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

less than 50 years old history of cigarette consumption

Upper limb involvement or migratory thrombophlebitis
Infra-popliteal vascular involvement

Exclusion criteria:

No burning pain and paresthesia at the time of referral
Symptoms of allergies and drug allergies More than 2-
fold increase in upper limit of liver enzymes More than 2-
fold increase in upper limit of renal function parameters
Lack of consent for continued intervention

Age

To 50 years old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 15

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical
Sciences

Street address

Deputy of Research and Technology of the University,
Qurashi Building, Next to Hoveyze Cinema,
University Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2021-04-24, 1400/02/04

Ethics committee reference number

IR.MUMS.REC.1400.025

Health conditions studied

1

Description of health condition studied

Buerger's disease

ICD-10 code

I73.1

ICD-10 code description

Thromboangiitis obliterans [Buerger's disease]

Primary outcomes

1

Description

Evaluation of pain using Visual Analogue Scale (VAS)
scoring method

Timepoint

every week

Method of measurement

questionnaire of Visual Analogue Scale of pain

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: receiving Noscapine 30 mg capsules
twice daily for 60 days + Common treatment (including
apixaban 5 mg/d and vitamin B1 300 mg/d)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Taheri's office located at 20 Daneshgah Street

Full name of responsible person

Dr Vahid Reza Askari

Street address

Mashhad university of medical science, Azadi square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries

Contact**Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Vahid Reza Askari

Position

Assistant professor of clinical pharmacology

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to

make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available