

# 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

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9177948564

**Phone**

+98 51 3800 2000

**Email**

askariv@mums.ac.ir

**Sponsors / Funding sources**

## 1

### Sponsor

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr Mohsen Tafaghodi

**Street address**

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

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**Phone**

+98 51 3841 2081

**Email**

ramresearch@mums.ac.ir

**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

**Street address**

Faculty of medicine, Paradise of University, Vakil-  
Abad Blvd., Azadi Sq., Mashhad

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askariv@mums.ac.ir

### Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr Vahid Reza Askari

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

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Faculty of Medicine, Azadi sq, Mashhad

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### Person responsible for updating data

**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr Vahid Reza Askari

**Position**

Assistant Professor

**Latest degree**

Ph.D.

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Medical Pharmacy

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**Postal code**

9177948564

**Phone**

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**Email**

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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