

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 May 2026

### Effect of topical Purslane (*Portulaca Oleracea*) on the pain intensity during cannulation among hemodialysis patients: double blind randomized clinical trial

#### Protocol summary

##### Study aim

Effect of purple ointment on the pain caused by fistula cannulation in hemodialysis patients

##### Design

Permuted block randomization (15 dual blocks) will be the randomization method.

##### Settings and conduct

This clinical trial will be carried out in the dialysis departments of the hospitals in Behlul, Gonabad and Imam reza Hospital in Mashhad. Due to the use of a tube with the same appearance, the patient will be blind. The researcher will be blind as a result of recording the pain score by the researcher's assistant.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age range of 18 to 60 years; awareness of time, place, and people at the time of data collection; basic literacy Exclusion criteria: damaged skin at the intended region; allergy to *Portulaca Oleracea*; alcohol and drug consumption history; history of mental illness.

##### Intervention groups

Both intervention and control groups consist of eligible diabetic patients who enter the study. In the intervention group, half an hour before the venipuncture, the place (equal to a square with the length of 5 cm) will be covered with some purslane ointment. Two minutes before the placement, the location was cleared for disinfection processes, and during the cannulation, the patient marked the pain score on a 100 mm scale ruler, and then the researcher's assistant measured the distance from the beginning of the ruler to the location of the mark and records it. The same process applies to the control group using placebo instead of purslane ointment.

##### Main outcome variables

pain

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20171219037966N2**

Registration date: **2018-04-14, 1397/01/25**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-07-30, 1397/05/08**

Update count: **1**

##### Registration date

2018-04-14, 1397/01/25

##### Registrant information

##### Name

Amirreza Nasirzadeh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 5722 3028

##### Email address

nasirzadeh@gmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-02-20, 1396/12/01

##### Expected recruitment end date

2018-05-20, 1397/02/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Effect of topical Purslane (Portulaca Oleracea) on the pain intensity during cannulation among hemodialysis patients: double blind randomized clinical trial

## Public title

Effect of topical Purslane (Portulaca Oleracea) on the pain intensity during cannulation in hemodialysis patients

## Purpose

Supportive

## Inclusion/Exclusion criteria

### Inclusion criteria:

Awareness of time, place and person at the time of data collection At least the reading and writing skills Age 18 to 60 years

### Exclusion criteria:

History of mental illness Alcohol drinking and drug use The presence of damaged skin in the desired position

## Age

From **18 years** old to **60 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Investigator
- Outcome assessor

## Sample size

Target sample size: **60**

## Randomization (investigator's opinion)

Randomized

## Randomization description

For randomization, the method of permuted blocks (15 dual blocks ) is used.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Patient: Due to the use of porphyry ointment and vitamin A as a placebo in tubes with similar appearance, patients can not distinguish between them. Researcher: The nurse is aware of the type of ointment used, but without knowing the researcher, they will be available to him. Due to the use of porphyry ointment and vitamin A as a placebo in tubes with similar appearance, researchers can not distinguish between them. Ex post evaluator: The ointment has been used by the researcher at the position and the evaluator is not aware of the type of ointment used for each patient.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Gonabad University of Medical Sciences

##### Street address

Gonabad University of Medical Sciences, Asian Roads, Gonabad, Khorasan Razavi, Iran

##### City

Gonabad

##### Province

Razavi Khorasan

##### Postal code

9691793718

#### Approval date

2018-01-03, 1396/10/13

#### Ethics committee reference number

IR.GMU.REC.1396.100

## Health conditions studied

### 1

#### Description of health condition studied

Chronic renal failure

#### ICD-10 code

N18.5

#### ICD-10 code description

Chronic kidney disease, stage 5

## Primary outcomes

### 1

#### Description

pain

#### Timepoint

First, second and third hemodialysis sessions

#### Method of measurement

Visual Analogue Scale

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: In the intervention group, half an hour before the venipuncture, the position will be covered with a 5 cm side squash with the help of a purslane ointment 10%. Two minutes before the placement, the location was cleared for disinfection processes, and during the cannulation, the patient marked the pain score on a 100 mm scale ruler, and then the researcher's assistant measured the distance from the beginning of the ruler to the location of the mark and

records it.

### Category

Treatment - Drugs

## 2

### Description

Control group: In the control group half an hour before the venipuncture, the position is covered with vitamin A ointment with a square of 5 cm side. Two minutes before the placement, the location was cleared for disinfection processes, and during the cannulation, the patient marked the pain score on a 100 mm scale ruler, and then the researcher's assistant measured the distance from the beginning of the ruler to the location of the mark and records it.

### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Reza hospital

##### Full name of responsible person

Hamid Dehghan Haqiqi

##### Street address

Imam Reza hospital, The margin of Imam Reza Square (AS), Ibn Sina St, Mashhad, Iran.

##### City

Mashahd

##### Province

Razavi Khorasan

##### Postal code

9691945182

##### Phone

+98 51 3802 2000

##### Email

Moalleg@gmail.com

### 2

#### Recruitment center

##### Name of recruitment center

Bohlol Hospital

##### Full name of responsible person

Hamid Dehghan Haqiqi

##### Street address

Gonabad University of Medical Sciences, Asian Roads, Gonabad, Khorasan Razavi, Iran

##### City

Gonabad

##### Province

Razavi Khorasan

##### Postal code

9691793718

##### Phone

+98 51 5722 3028

##### Email

h.dehghan.haqiqi@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Gonabad University of Medical Sciences

##### Full name of responsible person

Dr. Seyed Ali Sajjadi

##### Street address

Gonabad University of Medical Sciences, Asian Roads, Gonabad, Khorasan Razavi, Iran

##### City

Gonabad

##### Province

Razavi Khorasan

##### Postal code

9691793718 5 98+ تلفن

##### Phone

+98 51 5722 3028

##### Email

moalleg@gmail.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Gonabad 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

Gonabad University of Medical Sciences

##### Full name of responsible person

Amirreza Nasirzadeh

##### Position

Student

##### Latest degree

A Level or less

##### Other areas of specialty/work

Nursery

##### Street address

Gonabad University of Medical Sciences, Asian Roads, Gonabad, Khorasan Razavi, Iran

##### City

Gonabad

##### Province

Razavi Khorasan

##### Postal code

9691793718

**Phone**

+98 51 5722 3028

**Email**

nasirzadeh@gmu.ac.ir

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Gonabad University of Medical Sciences

**Full name of responsible person**

Mehdi Basiri Moghadam

**Position**

Master of science in Nursing

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

**Street address**

Gonabad University of Medical Sciences, Asian Roads,  
Gonabad, Khorasan Razavi, Iran

**City**

Gonabad

**Province**

Razavi Khorasan

**Postal code**

9691793718

**Phone**

+98 53 3733 2629

**Email**

basiri1344@gmail.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Gonabad University of Medical Sciences

**Full name of responsible person**

Amirreza Nasirzadeh

**Position**

Student

**Latest degree**

A Level or less

**Other areas of specialty/work**

Nursery

**Street address**

Gonabad University of Medical Sciences, Asian Roads,  
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**City**

Gonabad

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**Postal code**

9691793718

**Phone**

+98 51 5722 3028

**Email**

nasirzadeharnz@gmail.com

## 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