Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Nov 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)

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+98 51 5722 3028

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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.

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Mashahd

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2

Recruitment center

Name of recruitment center

Bohlol Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Dr. Seyed Ali Sajjadi

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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

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

Ŝtudent

Latest degree

A Level or less

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Full name of responsible person
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Master of science in Nursing

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Master

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Nursery

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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