

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 2026

Comparison the Effect of Thymus Vulgaris and Purslane (Portulaca Oleracea) Ointment on the pain intensity during cannulation

Protocol summary

Study aim

Comparison the Effect of Thymus Vulgaris and Purslane (Portulaca Oleracea) Ointment on the pain intensity during cannulation

Design

This trial has three parallel groups including the purslane group, the thyme group and the placebo group. The estimated sample size for this study is 48 people who will be divided into three groups by simple random sampling method.

Settings and conduct

The study will be conducted blindly at Gonabad University of Medical Sciences. In this study, the researchers are blind to the allocation of purslane and thyme and placebo blind groups. Demographic data and clinical status, scale were also collected to collect data. Visual pain will be used.

Participants/Inclusion and exclusion criteria

Age 18 years and over, at least 3 months history of hemodialysis, verbal, mental and visual disability, antinociceptive dependence, pre-cannulation pain, no analgesics, Thymus Vulgaris and purslane 24 hours before hemodialysis, no ulceration Fistula, no liver disorders, asthma, allergy and dermatitis, no known allergy or allergy to Thymus Vulgaris and purslane, no alcohol and drugs, no history of mental illness and hospitalization, are the criteria for entry. Patient's unwillingness to continue research, occurrence of any adverse drug reaction or response during intervention, failure to perform cannulation In the first act and the need for repeated cannulation, death or migration patient Exclusion criteria are

Intervention groups

The intervention group will use 5% purslane ointment and 5% Thymus Vulgaris ointment. The control group will receive placebo (vitamin A + D ointment).

Main outcome variables

Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181029041495N3**

Registration date: **2019-08-06, 1398/05/15**

Registration timing: **registered_while_recruiting**

Last update: **2019-08-06, 1398/05/15**

Update count: **0**

Registration date

2019-08-06, 1398/05/15

Registrant information

Name

Mohsen Aliakbari

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-27, 1398/05/05

Expected recruitment end date

2020-06-25, 1399/04/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the Effect of Thymus Vulgaris and Purslane (Portulaca Oleracea) Ointment on the painintensity during cannulation

Public title

Comparison the Effect of Thymus Vulgaris and Purslane (Portulaca Oleracea) Ointment on the painintensity during cannulation

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

18 years and older At least 3 months history of hemodialysis Verbal, mental and visual disability No dependence on analgesic drugs No pain before cannulation No use of painkillers, Thymus Vulgaris and purslane 24 hours before hemodialysis No wound in the fistula area Lack of liver disorders, asthma, allergies and dermatitis No known allergies or allergies to Thymus Vulgaris and purslane No use alcohol and drugs No record of mental illness and hospitalization in a psychiatric hospital

Exclusion criteria:

Patient's unwillingness to continue research The day of any adverse drug reaction or reaction during the intervention Failure to perform successful cannulation at first attempt and need to repeat cannulation Death or migration of the patient

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

For randomization, the 6-in-one reversal blocks method is used in three groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patient:Due to the use of purslane ointment and Thymus Vulgaris and vitamin A + D as placebo in tubes with similar appearance the patient is not able to distinguish them from each other.The researcher:The nurse is aware of the type of ointment used but gives the researcher no information. Due to the use of purslane ointment and Thymus Vulgaris and vitamin A + D as placebo in tubes with similar appearance the researcher is not able to distinguish them from each other.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,Iran

City

Gonabad

Province

Razavi Khorasan

Postal code

9691793718

Approval date

2019-07-28, 1398/05/06

Ethics committee reference number

IR.GMU.REC.1398.078

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

The first, second, third and fourth hemodialysis sessions

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:In the intervention groups, the

purslane group, the 5% purslane ointment, was rubbed 5 cm 21 minutes before needle insertion at the fistula site and covered with a transparent dressing. Thymus Vulgaris Group, 5% Thymus Vulgaris Ointment, will be rubbed 5 cm wide 21 minutes before needle insertion into the fistula and covered with a transparent dressing. Then in each group the ointment is completely cleaned and after disinfection of the area with 71% alcohol and iodine solution, intravenous cannulation is performed and pain intensity will be measured immediately by a trained nurse in all patients using a 100 mm gradient ruler.

Category

Prevention

2

Description

Control group: In the control group, vitamin A + D ointment will be rubbed for 21 minutes before the needle enters the fistula at 5 cm and covered with a transparent dressing. And the iodine solution, intravenous cannulation, and pain intensity will be measured immediately using a 100 mm calibrated ruler in all patients by a trained nurse.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic of Bohlool Gonabadi Hospital

Full name of responsible person

Mohsen Aliakbari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabad 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?

No

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

Fatemeh Ggholamian

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Position

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Latest degree

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Other areas of specialty/work

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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