

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparative study of the Effects of Emla Cream and Diclofenac Gel on Chemo Port Pain in patients Referring to Oncology wards in Zahedan University of Medical Sciences Affiliated Hospitals

Protocol summary

Summary

The aim of this study was to compare the effects of diclofenac gel and denture on pain caused by port insertion in patients undergoing chemotherapy in the Oncology Department of Zahedan University of Medical Sciences, Randomized, Double-blind, Controlled Patients. Entry criteria: willingness to participate in research; having verbal, subjective, vision; presently not having acute psychiatric disorders; history of fauxism; congenital idiopathic hemoglobinemia; liver disease; skin allergy; skin dermatitis; lack of treatment with sulfonamide, Nitrates and phenobarbital, non-diabetes, non-addiction, non-use of housing within the last 24 hours. Exit criteria: The wound of the port's location during the intervention; Infection and secretion at the port site during the intervention; Failure to reach the first action. Interventions: Diclofenac gel for 1 hour, one gram for one hour, one gram for 1 hour cream for 1 hour, vitamin A + D cream for one hour. Main outcome variable: diclofenac gel, spellet cream, vitamin A + D cream.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017080635520N1**
Registration date: **2017-08-30, 1396/06/08**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-08-30, 1396/06/08

Registrant information

Name

Alireza Salar

Name of organization / entity

Faculty of nursing and midwifery Zahedan

Country

Iran (Islamic Republic of)

Phone

+98 54 3344 2482

Email address

salar@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research zahedan University of Medical Sciences

Expected recruitment start date

2017-03-20, 1395/12/30

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of the Effects of Emla Cream and Diclofenac Gel on Chemo Port Pain in patients Referring to Oncology wards in Zahedan University of Medical Sciences Affiliated Hospitals

Public title

Comparative study of the Effects of Emla Cream and Diclofenac Gel on Chemo Port Pain in patients Referring to Oncology wards in Zahedan University of Medical Sciences Affiliated Hospitals

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: Inclination to participate in research; Having verbal, subjective, vision ability; At present there is no acute psychiatric disorder; There is no history of favism, congenital idiopathic hemoglobin, liver disease, skin allergy, skin dermatitis; no treatment with sulfonamides, nitrates Phenobarbital, non-diabetes, non-addiction, non-use of housing in the last 24 hours. Exit criteria: The wound of the port's location during the intervention; Infection and secretion at the port site during the intervention; Failure to follow the first action.

Age

From **12 years** old to **99 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size:

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

-

Secondary trial Id

-

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee Zahedan university of medical sciences

Street address

Administrative Complex of Khalij Fars Blvd. University of Medical Sciences, Dr Hasabi Square, Zahedan

City

Zahedan

Postal code

98167-43463

Approval date

2017-07-23, 1396/05/01

Ethics committee reference number

ir.zaums.rec.1396.103

Health conditions studied

1

Description of health condition studied

cancer

ICD-10 code

E2

ICD-10 code description

Neoplasms

Primary outcomes

1

Description

Emlacream

Timepoint

During the intervention

Method of measurement

Geram

2

Description

Diclofenac gel

Timepoint

During the intervention

Method of measurement

Geram

3

Description

Vitamin(A+D)

Timepoint

During the intervention

Method of measurement

Geram

Secondary outcomes

1

Description

Sex

Timepoint

During the intervention

Method of measurement

Patient case

2

Description

Duration under chemotherapy

Timepoint

During the intervention

Method of measurement

Day

3

Description

Age

Timepoint

During the intervention

Method of measurement

Years

4

Description

Severity of pain

Timepoint

During the intervention

Method of measurement

Vas

5

Description

Duration of port usage

Timepoint

During the intervention

Method of measurement

Day

Intervention groups

1

Description

diclofenac jel .1 geram.1 our once

Category

Treatment - Drugs

2

Description

emla cream .topical 1 geram.1ouronce

Category

Treatment - Drugs

3

Description

vitamin(A+D).1 geram.1 our once

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Oncology Department of Khatam-ol-Anbia Hospital in
Zahedan

Full name of responsible person

Shima Mohamadi Nejad

Street address

Khatam-al-Anbia Hospital, Khatam al-Anbia Square

City

Zahedan

2

Recruitment center

Name of recruitment center

Department of Oncology, Ali Ibn Abi Talib Hospital

Full name of responsible person

Shima Mohamadi Nejad

Street address

Dr. Ali Saba Hospital, Ali ibn Abi Talib

City

Zahedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research Zahedan University of
Medical Sciences

Full name of responsible person

Dr Nourmohammad Bakhshani

Street address

Administrative Complex of Khalij Fars Blvd. University
of Medical Sciences, Dr Hasabi Square, Zahedan

City

Zahedan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research Zahedan University of
Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Zahedan Nursing Midwifery Faculty

Full name of responsible person

Shima Mohammadinejad

Position

Master of Internal and Surgical

Other areas of specialty/work

Street address

Faculty of Nursing and Midwifery, Fellowship Square

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Zahedan Nursing Midwifery Faculty
Full name of responsible person
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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty