

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Comparing the effect of topical Lidocaine-Prilocaine cream and infiltrative Lidocaine on overall pain perception during thoracentesis and abdominocentesis

Protocol summary

Study aim

Study and comparison effect of topical anesthesia by Lidocaine/Prilocaine cream and local infiltrative Lidocaine in reducing pain during thoracentesis and abdominocentesis

Design

parallel, randomized, Clinical trial of 69 patients admitted to Al-Zahra Hospital in Isfahan in 2018 and 2019, for whom the attending physician ordered thoracentesis or abdominocentesis.

Settings and conduct

Interventional Radiology Department of Al-Zahra Hospital

Participants/Inclusion and exclusion criteria

Individuals whose attending physician has ordered a thoracentesis or abdominocentesis.

Intervention groups

thoracentesis infiltrative lidocaine/thoracentesis lidocaine-prilocaine cream abdominocentesis infiltrative lidocaine/abdominocentesis lidocaine-prilocaine cream

Main outcome variables

Patients' pain ,Patient satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191204045600N1**
Registration date: **2020-04-29, 1399/02/10**
Registration timing: **retrospective**

Last update: **2020-04-29, 1399/02/10**

Update count: **0**

Registration date

2020-04-29, 1399/02/10

Registrant information

Name

Hanieh Halili

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-20, 1397/12/01

Expected recruitment end date

2019-12-21, 1398/09/30

Actual recruitment start date

2019-02-20, 1397/12/01

Actual recruitment end date

2019-11-21, 1398/08/30

Trial completion date

2019-11-21, 1398/08/30

Scientific title

Comparing the effect of topical Lidocaine-Prilocaine cream and infiltrative Lidocaine on overall pain perception during thoracentesis and abdominocentesis

Public title

Anesthetic effect of topical lidocaine-prilocaine in thoracentesis and abdominocentesis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

patient undergoing thoracentesis or abdominocentesis, ordered by attending physician Alert Patients giving their consent to intervention

Exclusion criteria:

being pregnant or breast-feeding allergies to the amides
 having any dermatologic conditions at the site of
 procedure being G6PD using systemic analgesic
 medications

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **70**

Actual sample size reached: **69**

Randomization (investigator's opinion)

Randomized

Randomization description

With the help of Random Allocation Software, patients
 are randomly coded and divided into two groups by
 these codes.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

ethics committee of Isfahan Medical University

Street address

ethics committee of Isfahan Medical
 University, Hezarjarib Ave, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Approval date

2019-01-29, 1397/11/09

Ethics committee reference number

IR.MUI.MED.REC.1397.224

Health conditions studied**1****Description of health condition studied**

Pleural effusion

ICD-10 code

J91

ICD-10 code description

Pleural effusion in conditions classified elsewhere

2**Description of health condition studied**

Fluid in peritoneal cavity

ICD-10 code

R18

ICD-10 code description

Ascites

Primary outcomes**1****Description**

patient pain perception by using 0-10 Numeric Rating
 Scale

Timepoint

immediately after the procedure

Method of measurement

0-10 Numeric Rating Scale

2**Description**

patients' satisfaction level

Timepoint

immediately after the procedure, after asking pain
 perception

Method of measurement

1-4 scale

Secondary outcomes**1****Description**

number of attempts to perform paracentesis (either
 abdomocentesis or thoracentesis)

Timepoint

after the procedure

Method of measurement

Writing down the number of attempts

Intervention groups**1****Description**

Intervention group: Lidocaine-Prilocaine cream group
 received 2.5 gr from Lidocaine-Prilocaine cream. we used
 cream made by Tehranchemie.CO named Xayla-p.
 (100gr contain 2.5gr Lidocaine and 2.5gr Prilocaie). 2.5gr
 From this cream is a 9.5 cm strip of cream. That amount
 of cream is used to cover 20-25 cm² around the marked
 area. After 30 minutes procedure was done.

Category

Rehabilitation

2

Description

Control group: Infiltrative Lidocaine group received 5cc from lidocaine 2%(Caspian Tamin)(100mg) with a 25-gauge needle ,5 minutes before the procedure. Anesthetic is first injected subcutaneously and then deeper close to the parietal pleura in thoracentesis or to the peritoneum in abdominocentesis.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

ALzahra hospital, Isfahan

Full name of responsible person

Reza Azizkhani

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ALzahra hospital,Soffeh Blvd,Isfahan,Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo

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Isfahan University Of Medical Sciences,Hezarjarib Ave, Isfahan, Iran

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Hanieh Halili

Position

medical student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

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Full name of responsible person

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Person responsible for updating data

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Position

medical student

Latest degree

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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

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

study design, how data was collected, way of analyzing data ,and result of data analysis will be presented as means \pm SD, median (largest-smallest), and frequency (percentage of frequency)

When the data will become available and for how long

from the publication date in journal

To whom data/document is available

Who works in medical feilds

Under which criteria data/document could be used

medical doctors, medical nurses

From where data/document is obtainable

refere to the article which will be published .for more information they can contact Hanieh Halili (halili.hanie@yahoo.com) and Reza Azizkhani(azizkhani1980@gmail.com).

What processes are involved for a request to access data/document

from the publication date in journal they can refer to the journal for result of the study.

Comments