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)

Phone
+98 31 3778 9260

Email address
halili.hanie@yahoo.com

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
Isfehan

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 abdomonocentesis 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

Street address
ALzahra hospital,Soffeh Blvd,Isfahan,Iran

City
Isfahan

Province
Isfehan

Postal code
8174675731

Phone
+98 31 3620 2020

Email
alzahra@mui.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Shaghayegh Haghjoo

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

City
Isfahan

Province
Isfehan

Postal code
81746-73461

Phone
+98 31 3668 0048

Email
international@mui.ac.ir

Web page address

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

Street address
ALzahra hospital,Soffeh Blvd,Isfahan,Iran

City
Isfahan

Province
Isfehan

Postal code
8174675731

Phone
+98 31 3778 9260

Email
Halili.hanie@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Reza Azizkhani

Position
Professor

Latest degree
Specialist

Other areas of specialty/work
Emergency Medicine

Street address
ALzahra hospital,Soffeh Blvd,Isfahan,Iran

City
Isfahan

Province

Isfehan

Postal code

8174675731

Phone

+98 31 3620 2020

Email

azizkhani1980@gmail.com

Person responsible for updating data

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

Street address

ALzahra hospital,Soffeh Blvd,Isfahan,Iran

City

Isfahan

Province

Isfehan

Postal code

8174675731

Phone

+98 31 3778 9260

Email

Halili.hanie@yahoo.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

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 ± 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