Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The analgesic efficacy of lidocaine/prilocaine cream during fine-needle aspiration biopsy of thyroid nodules

Protocol summary

Study aim
Study of the analgesic effect of lidocaine/prilocaine cream during FNA of thyroid nodule

Design
The study has two parallel groups. It is performed using a randomized, double-blind, phase 3 method on 80 patients.

Settings and conduct
Patients who meet the entry criteria are accepted by the secretary of the ultrasound department and randomization is done by sealed cards using a block of 6 method. The professor in charge, who is not blind, will use the intervention cream or placebo for the patients. The patients will undergo FNA by the clinical assistant who is blind, and then will be asked about the amount of pain with a numerical rating scale.

Participants/Inclusion and exclusion criteria
In this study, 80 people who have been referred for needle biopsy of thyroid nodules for the first time with a minimum age of 18 years and a maximum age of 70 years will be included. Patients with nodules larger than one centimeter will be examined. Patients with altered mental status or inability to understand the questions, a history of long-term use of opioids or analgesics, or an allergy to the drug used in the study will be excluded.

Intervention groups
Intervention group: lidocaine + prilocaine 5% local anesthetic cream of Tehran Chemical Pharmaceuticals in the amount of 2.5 ml (~2.5 g) will be used in a thick layer on the biopsy site of the nodule 60 minutes before the procedure. Creams will be applied to the biopsy site in a specified and equal amount by the supervisor who knows the type of cream. Control group: Placebo cream consists of a white lotion (containing lubricant and Oserin) that is similar to lidocaine/prilocaine cream and will be used in the same amount and method as local anesthetic cream.

Main outcome variables
Pain level

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221212056796N1**
Registration date: **2023-04-15, 1402/01/26**
Registration timing: **prospective**

Last update: **2023-04-15, 1402/01/26**
Update count: **0**

Registration date
2023-04-15, 1402/01/26

Registrant information

Name
Sajjad Poursaleh

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-04-21, 1402/02/01

Expected recruitment end date
2023-06-21, 1402/03/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The analgesic efficacy of lidocaine/prilocaine cream during fine-needle aspiration biopsy of thyroid nodules

Public title
The analgesic efficacy of lidocaine/prilocaine cream during fine-needle aspiration biopsy of thyroid nodules
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients who have already done an ultrasound and the presence of thyroid nodules have been confirmed. Patients with a nodule larger than one centimeter
Exclusion criteria:
Altered mental state or inability to understand questions History of long-term use of opioids or painkillers Allergy to the drug which is used (Lidocaine/Prilocaine)
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, the permutation random block method will be used for randomization. For this purpose, a block of 6 will be used. In each block, the letter L (Lidocaine) is written on three cards, and the letter P (Placebo) is also written on three cards and is placed in a sealed envelope, the envelopes are selected randomly by Simple random sampling. The random blocks of 6 selected are as follows: PLPLLP, PPLPLL, LPPLLP, PLPLPL, LPPLLP, LPLLPP, PLLLPP, LPPLLP, PLLPPL, PPLPLL, LPLLPP, LLPLPP, LPPLLP. For example, the method of random allocation in the PLPLLP block of 6 is as follows: the first patient is assigned to treatment P, the second patient is assigned to treatment L, the third patient is assigned to treatment P, the fourth patient is assigned to treatment L, the fifth patient is assigned to treatment L, and the sixth patient is assigned to treatment P randomly.
Blinding (investigator's opinion)
Double blinded
Blinding description
The supervisor who is the main researcher, is responsible for giving different creams and she is not blind. A specialist clinical assistant is responsible for pain assessment and FNA procedure and he is blind. Information about the grouping of patients is not provided to the statistical analyst of the data and the study. The participants are fully informed about the procedure and the fact that they could be subject to treatment by analgesic cream or placebo cream. However, they are not aware of the type of cream used for them and this information is hidden from them.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Arak University of Medical Sciences
Street address
Valiasr hospital, Valiasr squre.
City
Arak
Province
Markazi
Postal code
3814957558
Approval date
2023-03-13, 1401/12/22
Ethics committee reference number
IR.ARAKMU.REC.1401.310

Health conditions studied

1

Description of health condition studied
Thyroid nodules
ICD-10 code
E04.1
ICD-10 code description
Nontoxic single thyroid nodule

Primary outcomes

1

Description
Numerical rating scale (NRS) will be used to check the pain level. The person rates their pain using a scale of 0 to 10. Zero means no pain and 10 means the worst pain condition.
Timepoint
Measuring the pain score after fine needle biopsy of thyroid nodules in patients who used lidocaine/prilocaine cream or placebo 60 minutes before the procedure.
Method of measurement
Asking the patient about the pain score from 0, the lowest to 10, the highest level of pain.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Lidocaine + prilocaine 5% local anesthetic cream of Tehran Chemical Pharmaceuticals in the amount of 2.5 ml (~2.5 grams) will be used uniformly in a thick layer on the biopsy site of the nodule 60 minutes before the procedure.
Category
Prevention

2

Description
Control group: Placebo cream consists of a white lotion (containing lubricant 5 g and Oserin 150 g) that looks like lidocaine/prilocaine cream. An amount of 2.5 ml (~2.5 g) will be used uniformly in a thick layer on the biopsy site of the nodule 60 minutes before the procedure.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr hospital of arak
Full name of responsible person
Fatemeh Safi
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Fax
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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?
Yes
Title of funding source
Arak 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
Arak University of Medical Sciences
Full name of responsible person
Sajjad Poursaleh
Position
Medical Resident
Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for updating data

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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