Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of use of lidocaine spray 10% on satisfaction of patients under spinal anesthesia.

Protocol summary

Study aim
The effect of lidocaine spray 10% on the satisfaction of patients under spinal anesthesia.

Design
Clinical trial phase 2 double-blind, placebo-controlled, randomized, with a sample size of 200

Settings and conduct
This study is performed on patients referred to the General Operating Room of Modarres hospital who are candidates for spinal anaesthesia. They are allocated to two groups: A and B. Patients in group A receive 10% lidocaine as local anaesthetic and patients in group II obtain an equivalent volume of normal saline. After 5 minutes, drug is removed from the skin and then the procedure is implemented. Relating to the type of spray, the patient and anesthesiologist and anaesthesia technician do not know the groups except for anesthesiologist responsible for handling the patients.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Indication of spinal anesthesia; ASA Class 1 (A normal healthy patient); Addiction to opium. exclusion criteria: Skin lesions at the needle insertion site; Patient dissatisfaction; Emergency surgeries.

Intervention groups
1-10% spray of lidocaine on the skin of people who are candidates for spinal anaesthesia before spinal needle insertion 2-spray of saline on the skin of people who are candidates for spinal anaesthesia before spinal needle insertion

Main outcome variables
Pain during spinal needle insertion; Anxiety during spinal needle insertion; Patient cooperation during spinal needle insertion; Patient satisfaction with spray use.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130120012203N11**
Registration date: **2020-01-21, 1398/11/01**
Registration timing: **retrospective**

Last update: **2020-01-21, 1398/11/01**
Update count: **0**

Registration date
2020-01-21, 1398/11/01

Registrant information

Name
Niloufar Massoudi

Name of organization / entity
Shahid Beheshti University of Medical Science

Country
Iran (Islamic Republic of)

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+98 26 3250 6961

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nmasoudi@qums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-04-04, 1396/01/15

Expected recruitment end date
2019-03-21, 1398/01/01

Actual recruitment start date
2017-03-21, 1396/01/01

Actual recruitment end date
2019-10-22, 1398/07/30

Trial completion date
2019-10-23, 1398/08/01

Scientific title
Evaluation of use of lidocaine spray 10% on satisfaction of patients under spinal anesthesia.

Public title

Effect of using lidocaine spray 10% on satisfaction of patients under spinal anesthesia.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Indication of spinal anesthesia ASA Class 1: A normal healthy patient Addiction to opium

Exclusion criteria:

Skin lesions at the needle insertion site Patient dissatisfaction emergency surgeries

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **200**

Actual sample size reached: **200**

More than 1 sample in each individual

Actual sample size in each individual: **1**

Every person who participates is counted as a sample.

Randomization (investigator's opinion)

Randomized

Randomization description

• Randomization method: Simple randomization • Randomization Component: Individual • Randomization instrument: computer-generated random numbers table. •allocation concealment: concealed in sequentially numbered, the similar canister with lidocaine and normal saline spry reserved by the anesthesiologist in the operating room.

Blinding (investigator's opinion)

Double blinded

Blinding description

Due to the similarity of the spray canister, the researcher and the patient are unaware of the type of spray material, but the anesthesiologist who performs the procedure and does not participate in the study knows the type of spray material that is marked with a colored label.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Modares Hospital.,Sadat Abade Blvd

City

Tehran

Province

Tehran

Postal code

1998734383

Approval date

2015-11-02, 1394/08/11

Ethics committee reference number

IR.SBMU.REC.1394.105

Health conditions studied

1

Description of health condition studied

pain

ICD-10 code

G89.18

ICD-10 code description

Other acute post procedural pain

Primary outcomes

1

Description

Acute pain

Timepoint

At the end of surgery

Method of measurement

Visual Analogue Scale (VAS)

Secondary outcomes

1

Description

Anxiety

Timepoint

At the end of surgery

Method of measurement

Anxiety with Zank questionnaire

2

Description

Cooperation

Timepoint

At the end of surgery

Method of measurement

The rate of cooperation with the questionnaire

3

Description
satisfaction
Timepoint
At the end of surgery
Method of measurement
Using the questionnaire

Intervention groups

1

Description
Intervention group: The lidocaine spray 10% is scattered 5 minutes before the spinal anesthesia is implemented at the injection site.
Category
Treatment - Drugs

2

Description
Control group: spry normal saline is scattered 5 minutes before the spinal anesthesia is implemented at the injection site.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Modares Hospital
Full name of responsible person
Nilofar Massoudi
Street address
Modarres Hospital., Saddat Abade Blvd., Kaj Square.,
City
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Tehran
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massodi@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Nilofar Massoudi
Street address
Modarres Hospital., Saddat Abade Blvd., Kaj Square
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Fax
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Email
massodi@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Nilofar Massoudi
Position
Assistance Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Modarres Hospital., Saddat Abade Blvd., Kaj Square.,
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Person responsible for scientific

inquiries

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Shahid Beheshti University of Medical Sciences

Full name of responsible person
Nilofar Massoudi

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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Person responsible for updating data

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Email
massodi@sbmu.ac.ir

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Part of the data, such as information about its main consequence, can be shared.

When the data will become available and for how long
The access period will be 6 months after the results are published

To whom data/document is available
Researchers working in academic and scientific institutions will be available.

Under which criteria data/document could be used
When using data for further studies such as meta-analysis

From where data/document is obtainable
Dr. Nilofar Massoudi massodi@sbmu.ac.ir Modarres Hospital., Saddat Abade Blvd., Kaj Square +98 21 2207 4087

What processes are involved for a request to access data/document
List the requested information in full identification with email and then email it in response to information other than data that identify patients.

Comments