

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effect of adding dexamethasone to lidocaine in digital block in patients referred to the operating room of AJA 501 hospital

Protocol summary

Study aim

Evaluation of the effect of adding dexamethasone to lidocaine in digital finger block in patients referred to the operating room of AJA 501 hospital

Design

This study is a double blind RCT (clinical trial) on 60 patients randomly assigned using black and white cards in two parallel groups (30 people in each group), so that patients with black card to group one, And patients with white cards are assigned to group two and this process is repeated again.

Settings and conduct

Patients aged 20-60 years who have referred to the operating room of 501 AJA Hospital for finger surgery. After the operation and in the operating room recovery, the studied variables are recorded in the relevant questionnaire by the person in charge of collecting information who does not know the content of the syringes in the two groups.

Participants/Inclusion and exclusion criteria

All patients aged 20 to 60 years and ASA I who refer to the operating room of 501 Aja Hospital in Tehran electively or urgently from the time the plan is approved to perform surgery on one of the fingers and consciously sign the written consent form to participate in the research plan. Non-entry conditions: People with a history of allergies to local anesthetics - Pregnant women - People with a history of diabetes or uncontrolled liver and kidney disease - People with hemodynamic instability - People with a history of peptic ulcer - People on long-term treatment with corticosteroids.

Intervention groups

Depending on the color of the patient's black or white card, 3 cc of 2% lidocaine plus 1 cc (equivalent to 4 mg) of dexamethasone or 3 cc of 2% lidocaine plus 1 cc of distilled water is filled. The finger becomes relevant and starts 10 minutes after the surgeon performs the surgical block

Main outcome variables

1- FPP (free pain period) 2- Intensity of pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110103005536N9**

Registration date: **2020-09-24, 1399/07/03**

Registration timing: **registered_while_recruiting**

Last update: **2020-09-24, 1399/07/03**

Update count: **0**

Registration date

2020-09-24, 1399/07/03

Registrant information

Name

Mohamadreza Rafiei

Name of organization / entity

Artesh University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8802 8933

Email address

mo_rafiee@armyums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-21, 1397/01/01

Expected recruitment end date

2021-03-19, 1399/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of adding dexamethasone to lidocaine in digital block in patients referred to the operating room of AJA 501 hospital

Public title

Evaluation of the effect of adding dexamethasone to lidocaine in digital block

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

All patients 20 to 60 years ASA |

Exclusion criteria:

History of allergy to local anesthetic pregnancy People with a history of diabetes or uncontrolled liver and kidney disease People with hemodynamic instability people with history of peptic ulcer People on long-term treatment with corticosteroids.

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

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

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomly assigned by sampling method and using black and white cards are divided between the two groups (30 people in each group), so that patients with black card are assigned to group one, and patients with white card are assigned to group two. Given and this process is repeated again

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, neither the patient nor the collector knew how the samples were distributed. The obtained information is then statistically analyzed by the person in charge of statistical work who does not know how the patients are distributed.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of aja university of medical sciences

Street address

Etemadzadeh St. , West Fatemi Ave.

City

Tehran

Province

Tehran

Postal code

8158177365

Approval date

2016-08-01, 1395/05/11

Ethics committee reference number

IR.AJAUMS.REC.1395.11

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

Digital nerve block

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

FPP (Free Pain Period)

Timepoint

When the patient requests an analgesic

Method of measurement

Duration of the patient's analgesic period in hours

2**Description**

Intensity of pain

Timepoint

During the intervention

Method of measurement

According to the instruction given to all patients on how to express pain intensity according to the equivalent of visual equivalent (Visual Analogue Scale) through a 100 mm ruler, patients express their pain intensity as grade I≤30 (mild pain) and grade <30 II≤70 (Moderate pain) Grade III is divided into <70 (severe pain)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In one group, depending on the color of the patient's black or white card, participating in the project of 3 cc of 2% lidocaine plus 1 cc (equivalent to 4 mg) of dexamethasone, a digital finger block is performed and 10 minutes after the block Surgery is started by a surgeon

Category

Treatment - Drugs

2

Description

Intervention group: In one group, depending on the color of the patient's black or white card, participating in the project, 3 cc of 2% lidocaine plus 1 cc of distilled water will perform a digital finger block and 10 minutes after the surgical block, the surgeon will start the operation.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

501AJA hospital

Full name of responsible person

Dr. Mohammadreza rafiei

Street address

Etemadzadeh St. , West Fatemi Ave.

City

Tehran

Province

Tehran

Postal code

1411718546

Phone

+98 21 6350 8609

Email

mo_rafiei@armyums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

Saeed Soleyman Meygooni

Street address

Etemadzadeh st. , West Fatemi Ave.

City

Tehran

Province

Tehran

Postal code

1411718541

Phone

+98 21 6350 8609

Email

mo_rafiei@armyums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Artesh 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

Artesh University of Medical Sciences

Full name of responsible person

Mohamadreza Rafiei

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Etemadzadeh street. West fatemi

City

Tehran

Province

Tehran

Postal code

8158177365

Phone

+98 21 8802 8933

Fax

+98 31 1263 1587

Email

mo_rafiei@armyums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

Mohamadreza Rafiei

Position

Associate professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Etemadzadeh St. West Fatemi Ave.
City
Tehran
Province
Tehran
Postal code
8158177365
Phone
+98 21 8802 8933
Fax
+98 31 1263 1587
Email
mo_rafiei@armyums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Artesh University of Medical Sciences
Full name of responsible person
Mohammadreza Rafiei
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Etemadzadeh St. West Fatemi Ave.
City
Tehran
Province
Tehran
Postal code

8158177365
Phone
+98 21 8802 8933
Fax
+98 31 1263 1587
Email
mo_rafiei@armyums.ac.ir

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

Not applicable

Title and more details about the data/document

All data can be shared after being unidentified

When the data will become available and for how long

Start the access period after printing the results

To whom data/document is available

All researchers and colleagues in this field

Under which criteria data/document could be used

For therapeutic and research purposes and by mentioning the names of the authors of the article

From where data/document is obtainable

Dr. Mohammadreza rafiei

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

Send email to Dr. Mohammad Reza Rafiei and receive data and documents if needed in the shortest time

Comments