Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jul 2026

Evaluating the effect of adding Dexamethasone / TNG to Lidocaine on the quality of Intra-Venous Regional Anesthesia (IVRA)

Protocol summary

Summary

Objective: Evaluating the effect of adding Dexamethasone/TNG to Lidocaine on the quality of Intravenous Regional Anesthesia (IVRA). Study design: In a single central, prospective trial, 90 patients will randomly be allocated into 3 groups. Each group will comprise of 30 cases. The control group, L, will only receive Lidocaine. The intervention group of LD will receive Lidocaine plus Dexamethasone; and the intervention group of LN will receive Lidocaine plus TNG.The study will be blinded from researchers' and patients' side (double blind study). Main inclusion criteria: Male or female patients; scheduled for hand or forearm surgery with I & II physical status of ASA; aged between 20 and 50 years. Main exclusion criteria: Patients with sickle cell anemia; Raynaud's disease; history of drug allergy. Setting and conduct: Following the basic preparation for intravenous regional anesthesia IVRA, group L will receive 3 mg/kg up to maximum 200 mg of Lidocaine, group LD besides to Lidocaine (similar to group L) will receive 8 mg of Dexamethosone, and group NL besides to Lidocaine (similar to group L) will receive 200 µg of Nitroglycerin. Outcomes: As primary outcomes, the onset and the recovery times from sensory and motor blocks, and the starting time of tourniquet pain will be measured. As secondary outcomes, the amount of the required narcotics during patients’ recovery and probable side effects will be measured. The results will be compared between the three groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015053122511N1**
Registration date: **2015-10-04, 1394/07/12**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2015-10-04, 1394/07/12

Registrant information

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Urmia University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Urmia University of Medical Sciences

Expected recruitment start date

2014-01-01, 1392/10/11

Expected recruitment end date

2014-10-16, 1393/07/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of adding Dexamethasone / TNG to Lidocaine on the quality of Intra-Venous Regional Anesthesia (IVRA)

Public title

Evaluating the quality of Intra-Venous Regional Anesthesia (IVRA) following adding Dexamethasone or TNG to Lidocaine

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: male or female patients; scheduled for hand or forearm surgery with I & II physical status of ASA; aged between 20 and 50 years. Exclusion criteria: Patients with sickle cell anemia; Raynaud's disease; history of drug allergy.
Age
From **20 years** old to **49 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Patients will randomly be allocated to one of the three groups of Lidocaine (L), Lidocaine + Dexamethasone (LD), Lidocaine + TNG (LN); each group will be comprising of 30 cases.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
research ethical Committee of Urmia university of medical sciences
Street address
Emam Khomini Hosp. Homafar Bulv.
City
Urmia
Postal code
Approval date
2014-06-19, 1393/03/29
Ethics committee reference number
94/4/17376 /6/پ

Health conditions studied

1

Description of health condition studied
Intravenous Regional Anesthesia
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
The onset time of sensory block
Timepoint
every 30 sec.
Method of measurement
Pinprick test

2

Description
The onset time of motor block
Timepoint
every minute
Method of measurement
ability to flex and exten wriet and fingures

3

Description
The onset time of tourniquet pain
Timepoint
in 1, 5, 10, 20, and 30 minutes
Method of measurement
visual analog scale of pain

4

Description
The recovery time from sensory block
Timepoint
every 30 sec.
Method of measurement
Pinprick test

5

Description
The recovery time from motor block
Timepoint
in 1, 5, 10, 20, and 30 minutes
Method of measurement
ability to flex and exten wriet and fingures

Secondary outcomes

1

Description
The amount of analgesic consumptions
Timepoint
If patient reported VAS>3
Method of measurement
1 micro gr/kg

Intervention groups

1

Description
Control: 3 mg/kg Lidocaine (max: 200mg)
Category
Treatment - Drugs

2

Description
Intervention 1: 3mg/kg Lidocaine (max: 200mg)+ 200 microgram TNG
Category
Treatment - Drugs

3

Description
Intervention 2: 3 mg/kg Lidocaine (max: 200mg)+ 8 mg Dexamethasone
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam academic hosptial
Full name of responsible person
Dr. Ebrahim Hassani
Street address
Homafar Bolv.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Urmia University of Medical Sciences
Full name of responsible person
Dr. Iraj Mohebbi
Street address
Vice chancellor of research affairs at UMSU
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Urmia
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Urmia University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty