

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Comparison of wide awake local anesthesia(WALANT) and bier block on hand surgery

Protocol summary

Study aim

The study hypothesis is that Wide awake local anaesthesia no tourniquet technique (WALANT) and forearm BIER block are safe, inexpensive and suitable alternative to the conventional anesthesia techniques for hand surgeries.

Design

Two arm parallel group randomised trial design of 86 patients, enrolled between June 2018 and September 2018

Settings and conduct

This study will be performed on 86 ASA class I-III patients between the ages of 20--65 years who are undergoing hand and wrist surgeries. After obtaining of an informed consent, patients will be allocated to two groups by stratified random sampling.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: 20--65 years old patients undergoing hand surgeries
Exclusion Criteria: psychologic patients, addiction, history of allergy to local anesthetics, epilepsy, history of peripheral vascular disease, coagulopathy, pregnancy, open wound in operation site

Intervention groups

In the WALANT group, 20 ml solution including lidocaine 1% and epinephrine (5 Mg/ml) and sodium bicarbonate (50mg/2ml) will be injected into operation site. Injection will be done by a 27_gauge needle. In the Bier block group (IRIV), a 22G cannula will be secured on the dorsum of the operative hand. The single cuff tourniquet will be then placed around the forearm and inflated to a pressure of 100 mmHg above the patient's systolic blood pressure and minimum of 250 mmHg. IRIV will be achieved with 25 lidocaine 0.5 % plus fentanyl 50 Mg. The sensory block will be evaluated with pinprick testing every 30 s until the start of surgery.

Main outcome variables

Determination of WALANT effects on analgesia, complications, patient satisfaction, surgery site bleeding, need to additional IV sedation and analgesics and

comparison them with forearm BIER block group.

General information

Reason for update

Acronym

WALANT-BEER

IRCT registration information

IRCT registration number: **IRCT20180325039148N2**

Registration date: **2018-06-09, 1397/03/19**

Registration timing: **registered_while_recruiting**

Last update: **2018-06-09, 1397/03/19**

Update count: **0**

Registration date

2018-06-09, 1397/03/19

Registrant information

Name

Saeed Jalili

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 24 3313 0001

Email address

jalilis45@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-22, 1397/03/01

Expected recruitment end date

2018-09-22, 1397/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of wide awake local anesthesia(WALANT) and bier block on hand surgery

Public title

Effect of regional anesthesia in Hand surgery

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

20-65 Years old Hand surgery

Exclusion criteria:

Psychologic disease Pregnancy Raynod disease
Peripheral vascular disease Addiction Open wound
Allergy to local anesthetics Epilepsy Coagulation disease

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **86**

Randomization (investigator's opinion)

Randomized

Randomization description

stratified randomization

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients,Analysers of Data

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Zanjan University of Medical Sciences

Street address

Gavazannng Blvd., Moosavi Hospital

City

Zanjan

Province

Zanjan

Postal code

4513956183

Approval date

2018-03-06, 1396/12/15

Ethics committee reference number

IR.ZUMS.REC.1396.310

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

Carapal Tunnel Syndrome

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

Determination of of local anesthesia and analgesia in hand surgery

Timepoint

Beginnig of surgery_During of surgery_Recovery unit

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups**1****Description**

1st Intervention group : Under local anesthesia ,awake and without tourniquet (WALANT) ,20 ml solution including lidocaine 1% and einephrine(5Mg/ml) and sodium bicarbonate (50mg/2ml) will be injected into operation site.Injection will be done by a 27_gauge needle.

Category

Treatment - Surgery

2**Description**

2nd Intervention group:A 22G cannula will be secured on the dorsum of the operative hand, after which, limb exsanguination will be achieved with an esmarch bandage . The single cuff tourniquet will be then placed around the forearm and inflated to a pressure of 100 mmHg above the patient's systolic blood pressure and to a minimum of 250 mmHg. Circulatory isolation of the operative arm was confirmed by absence of radial .IRIV will be achieved with 25 lidocaine 0.5 % plus fentanyl 50 Mg.The sensory block will be evaluated with pinprick testing every 30 s until the start of surgery.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Mousavi Hospital

Full name of responsible person

Saeed Jalili

Street address

Gavazang Blvd., Mosavi Hospital

City

Zanjan

Province

Zanjan

Postal code

4513956183

Phone

+98 24 3313 0000

Fax

+98 24 3313 1203

Email

jalilis45@zums.ac.ir

Web page address

http://zums.ac.ir/index.php?slc_lang=fa&sid=19

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Shoghli Alireza

Street address

Gavazang Blvd., Mousavi hospital

City

Zanjan

Province

Zanjan

Postal code

4513956183

Phone

+98 24 3313 0000

Fax

+98 24 3313 1203

Email

jalilis45@zums.ac.ir

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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

Zanjan 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

Zanjan University of Medical Sciences

Full name of responsible person

Jalili Saeed

Position

Consultant, Professor, Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Gavazang Blvd., Mousavi hospital

City

Zanjan

Province

Zanjan

Postal code

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Phone

+98 24 3313 0000

Fax

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Email

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Jalili Saeed

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Gavazang Blvd., Mousavi hospital

City

Zanjan

Province

Zanjan

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

Saeed Jalili

Position

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Latest degree

Specialist

Other areas of specialty/work

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Street address

Gavazang Blvd., Moosavi hospital

City

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Province

Zanjan

Postal code

4513956183

Phone

+98 24 3313 0001

Fax

+98 24 3313 1203

Email

jalilis@ymail.com

Web page address

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not 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