

# 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**

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**Postal code**

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**Phone**

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**Email**

jalilis45@zums.ac.ir

**Web page address**

[http://zums.ac.ir/index.php?slc\\_lang=fa&sid=19](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

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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

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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

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

Zanjan University of Medical Sciences

**Full name of responsible person**

Saeed Jalili

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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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