

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### Comparing the effectiveness of adding dexmedetomidine to standard Walant solution in local anesthesia of patients with distal radius fracture on postoperative complications.

#### Protocol summary

##### Study aim

Comparison of the results of using Walant solution together with dexmedetomidine on block duration, block initiation and postoperative analgesia with Walant solution alone in distal radius fracture surgery

##### Design

بی حسی موضعی بیدار کامل بدون) WALANT در یک گروه تکنیک های استفاده از تورنیکت) در محل جراحی و در گروه دیگر همین تکنیک که به آن محلول دکسمدتومیدین اضافه شده است تزریق می شود

##### Settings and conduct

After transferring the patient to the operation room of Shahada Tajrish hospital and standard monitoring and fluid therapy, oxygen 5 lit/min is prescribed through a mask and then Walant solution containing 20 ml of lidocaine 2% along with 2 CC of epinephrine vial 1000/01 to Along with 14 CC of normal saline and 4 CC of 8.4% sodium bicarbonate (40 CC in total) for the control group and the same solution plus 5 micrograms per kilogram of body weight of dexmedetomidine for the intervention group is injected at the operation site.

##### Participants/Inclusion and exclusion criteria

Patients aged 18 to 80 years with distal radius fracture are included in the study, and patients with active site infection, peripheral vascular disease, anxiety, severe fear of injection, impaired coagulation profile, open fracture, and fracture more than 3 weeks old are excluded

##### Intervention groups

In the control group, surgery with local anesthesia of Walant solution containing 20 ml of lidocaine 2% along with 2 CC of epinephrine 01/1000 vial along with 14 CC of normal saline and 4 CC of sodium bicarbonate 8.4%, a total of 40 CC and in the group The intervention of this solution plus 5 micrograms per kilogram of dexmedetomidine is used

##### Main outcome variables

The amount of pain during and after surgery, the

hemodynamic status during surgery, the amount of bleeding during surgery and the limitation of wrist movements after surgery

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210216050379N4**

Registration date: **2023-04-05, 1402/01/16**

Registration timing: **prospective**

Last update: **2023-04-05, 1402/01/16**

Update count: **0**

##### Registration date

2023-04-05, 1402/01/16

##### Registrant information

##### Name

Hamidreza Azizifarsani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2274 1174

##### Email address

h.faresani@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-04-09, 1402/01/20

##### Expected recruitment end date

2023-09-23, 1402/07/01

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparing the effectiveness of adding dexmedetomidine to standard Walant solution in local anesthesia of patients with distal radius fracture on postoperative complications.

**Public title**

New technique of distal radius surgery

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Distal radius fracture requiring surgery for fixation

**Exclusion criteria:**

Active surgical site infection Peripheral vascular disease anxiety Impaired coagulation profile Phobia of injections

**Age**

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

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **40**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Block randomization will be done by dividing included patients into some blocks of size  $2n$  (2,4,6,8 and...), then randomizing patients in each block will be done such that  $n$  patients are allocated to the experimental group and control group. then we will choose the blocks randomly. This method ensures equal treatment allocation within each block when the complete block is used.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****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**

Velenjak street

**City**

Tehran

**Province**

Tehran

**Postal code**

1983969411

**Approval date**

2022-07-24, 1401/05/02

**Ethics committee reference number**

IR.SBMU.RETECH.REC.1401.281

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

Distal radius fracture

**ICD-10 code**

S52.5

**ICD-10 code description**

Fracture of lower end of radius

**Primary outcomes****1****Description**

Pain

**Timepoint**

During and immediately after surgery

**Method of measurement**

Visual analogue scale

**2****Description**

Hemodynamic status during surgery

**Timepoint**

During surgery

**Method of measurement**

Monitoring during surgery

**3****Description**

Bleeding volume during surgery

**Timepoint**

during surgery

**Method of measurement**

Blood volume measurement

**Secondary outcomes**

empty

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

Intervention group: For patients with distal radius fractures, Walant solution containing 20 ml of 2% lidocaine with 2 CC of 1000/01 epinephrine vial, 14 CC of normal saline and 4 CC of 8.4% sodium bicarbonate (40 CC in total) and the same solution in addition 50 micrograms per kilogram of their weight, dexmedetomidine is injected at the site of operationp:

#### Category

Treatment - Surgery

### 2

#### Description

Control group: patients with distal radius fracture who received Walant solution with WALANT technique (full awake local anesthesia without using tourniquet) including 20 ml lidocaine 2% with 2 CC of epinephrine 01/1000 vial, with 14 CC of normal saline and 4 CC They receive 8.4% sodium bicarbonate (40 CC in total) at the surgical site

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shohada Tajrish Hospital

##### Full name of responsible person

Hamidreza Azizifarsani

##### Street address

Tajrish squire

##### City

Tehran

##### Province

Tehran

##### Postal code

1989934148

##### Phone

+98 21 2238 2080

##### Email

h.faresani@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Vice chancellor for research,Afshin Zarghi

##### Street address

Bldg, No2, Shahid Beheshti University of Medical sciences, Arabi Ave, Daneshjoo Blvd, velenjak,

##### City

Tehran

##### Province

Tehran

##### Postal code

1981958379

##### Phone

+98 21 2243 2572

##### Email

h.faresani@gmail.com

##### 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

Hamidreza Azizifarsani

##### Position

Assistant professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Anesthesiology

##### Street address

NO.1,Shahid Lamee st, Faraze, Tehran

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##### Province

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##### Postal code

1981956316

##### Phone

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Hamidreza Azizifarsani

##### Position

Assistant Professor

##### Latest degree

Specialist

**Other areas of specialty/work**

Anesthesiology

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

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Hamidreza Azizifarsani

**Position****Latest degree**

Specialist

**Other areas of specialty/work**

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

Undecided - It is not yet known if there will be a plan to make this available

**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