

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)

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+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

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Tajrish squire

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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

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

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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

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

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Person responsible for scientific inquiries

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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