Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Walant technique for clavicle fracture fixation with anatomic locking plate with diameter 3.5 millimeters

Protocol summary

Study aim

Evaluation of the results of using the walant technique in open surgery of clavicle fractures with the help of a plate with a diameter of 3.5 mm

Design

Phase 2 clinical trial in patients with acute clavicle fractures requiring fixation surgery that the control group does not have.

Settings and conduct

Included patients will be transferred to the operating room and first WALANT solution is injected for them and then the patients are transferred to the operating table and undergo surgery. The WALANT is 200 cc of a solution containing 50 ccs of 1% lidocaine and 5 ccs of 7.5% sodium bicarbonate, 1 cc of adrenaline, and normal saline.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients aged 16 to 60 years with acute clavicle fractures require fixation surgery. Exclusion criteria are patients with cardiovascular problems or with a history of seizure and psychiatric problems, open fractures, fractures with vascular-neurological damage, and other serious injuries in the shoulder girdle.

Intervention groups

Patients aged 16 to 60 years with acute clavicle fractures require fixation surgery operated with open clavicle surgery with WALANT techniques (wide awake local anesthesia no tourniquet)

Main outcome variables

During and after the operations, various factors such as pain, bleeding and range of motion, patient activity, and surgical complications are collected by a pre-prepared questionnaire.During the patient's hospitalization, we consider and follow the patient's bleeding volume and wound problems.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211201053235N2**
Registration date: **2022-01-27, 1400/11/07**
Registration timing: **prospective**

Last update: **2022-01-27, 1400/11/07**
Update count: **0**

Registration date

2022-01-27, 1400/11/07

Registrant information

Name

Meisam Jafari Kafiabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2271 8000

Email address

dr.jafari8567@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-05, 1400/11/16

Expected recruitment end date

2022-05-06, 1401/02/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Walant technique for clavicle fracture fixation with anatomic locking plate with diameter 3.5 millimeters

Public title
Open surgical treatment of clavicle fractures
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Acute clavicle fracture requires fixation surgery
Exclusion criteria:
Patients with cardiovascular problems Patients with history of seizure Patients with history of psychiatry disorders Patients with open clavicle fractures Fractures associated with vascular-neurological damage Serious injury to the shoulder girdle
Age
From **16 years** old to **60 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
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
Shahid Beheshti University of Medical Sciences, Yemen Street, Shahid Chamran Highway, Iran, Tehran
City
Tehran
Province
Tehran
Postal code
1983969411
Approval date
2022-01-09, 1400/10/19
Ethics committee reference number
IR.SBMU.RETECH.REC.1400.764

Health conditions studied

1

Description of health condition studied
Fracture of clavicle
ICD-10 code
S42.0
ICD-10 code description
Fracture of clavicle

Primary outcomes

1

Description
Pain
Timepoint
2 weeks, 6 weeks, 12 weeks and 6 and 12 months after surgery
Method of measurement
visual analogue scale

2

Description
bleeding volume during surgery
Timepoint
2 weeks, 6 weeks, 12 weeks and 6 and 12 months after surgery
Method of measurement
Blood volume measurement

3

Description
union of bones
Timepoint
2 weeks, 6 weeks, 12 weeks and 6 and 12 months after surgery
Method of measurement
Assessment of the bony cortex on radiography

4

Description
Duration of hospitalization
Timepoint
2 weeks, 6 weeks, 12 weeks and 6 and 12 months after surgery
Method of measurement
Patients records

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients with open clavicle fracture surgery with the help of plaque with a diameter of 3.5 mm and anesthesia injection technique of 200 cc of solution containing 50 cc of 1% lidocaine and 5 cc of sodium bicarbonate 7.5%, 1 cc of adrenaline and normal saline

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Shohada Tajrish Hospital

Full name of responsible person
Dr. Meisam Jafari Kafiabadi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Afshin Zarghi

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Yemen street, Chamran highway, Tehran

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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
Meisam Jafari Kafiabadi

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Orthopedics

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
After finishing patient recruitment

When the data will become available and for how long
After finishing patient recruitment

To whom data/document is available
After finishing patient recruitment

Under which criteria data/document could be used
After finishing patient recruitment

From where data/document is obtainable
After finishing patient recruitment

What processes are involved for a request to access data/document
After finishing patient recruitment

Comments
After finishing patient recruitment