Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effect of Vitamin D on Grip Power in Menopausal Women with Distal Radius Fractures

Protocol summary

Study aim
Effect of vitamin D on grip power in menopausal women with distal radius fracture

Design
This study is a clinical trial which will be conducted on postmenopausal women with Distal Radius Fractures. The sample size is computed to be 42 clients in each group according to previous studies, and 95% confidence level.Patients will randomly be divided into two intervention and control groups.

Settings and conduct
This study will be conducted at Imam Khomeini hospital in Sari, Iran. Patients will enter the study after obtaining informed consent and according to inclusion and exclusion criteria they will be divided into two groups of intervention and control by random numbers table. The Grip strength will be measured by the dynamometer. According to the patient's pain and the likelihood of their lack of cooperation, grip strength will be measured in the opposite hand, according to 10% law, grip strength of broken hand will be 10% less than healthy hand. Then Vitamin D 50,000 units will be administrated every 4 weeks for 3 months.

Participants/Inclusion and exclusion criteria
Inclusion criteria:Menopausal women aged over 50 years؛ Fracture of the end of radius؛ levels of vitamin D before surgery 30 -100ng / ml؛ Patient's informed consent to participate in the study؛ No treatment in the last 6 months; Exclusion criteria: Digestive diseases؛ Kidney diseases such as acute and chronic failure and ESRD؛ Rheumatic diseases

Intervention groups
Intervention group: Vitamin D, 50,000 units, every 4 weeks for 3 months. Control group:No Vitamin D will be administrated.

Main outcome variables
Grip power

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160830029603N7**
Registration date: **2018-07-12, 1397/04/21**
Registration timing: **registered_while_recruiting**

Last update: **2018-07-12, 1397/04/21**
Update count: **0**

Registration date
2018-07-12, 1397/04/21

Registrant information

Name
Masoud Shayestehazar

Name of organization / entity
Mazandaran University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 11 3304 4859

Email address
shayestehazar@mazums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-11-22, 1396/09/01

Expected recruitment end date
2018-11-22, 1397/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of Vitamin D on Grip Power in Menopausal Women with Distal Radius Fractures

Public title
Effect of Vitamin D on Grip Power in Menopausal Women
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Menopausal women aged over 50 years. Fracture of the end of radius Level of vitamin D equal to 30 -100ng/ml before surgery Patient's informed consent to participate in the study No treatment in the last 6 months
Exclusion criteria:
Digestive diseases Kidney diseases such as acute and chronic failure and ESRD Rheumatic diseases Patients with traumatic, neoplastic or infectious lesions history of surgery History of Diabetes History of disabling background problems
Age
From **50 years** old
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **84**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization using Random Numbers Table
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Mazandaran University of Medical Sciences
Street address
Mazandaran University of Medical Sciences, First of Vali Asr high way, Joibar three way, Emam Sq.
City
Sari
Province
Mazandaran
Postal code
۳۳۹۷۱-۴۸۱۵۷
Approval date
2017-03-13, 1395/12/23
Ethics committee reference number
IR.MAZUMS.IMAMHOSPITAL.REC.1396.3079

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
Grip strength
Timepoint
Measure the grip strength of the patients before the intervention and 2, 6, 12, 24 weeks after administration of vitamin D
Method of measurement
dynamometer

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Vitamin D 50,000 units every 4 weeks for 3 months
Category
Treatment - Drugs

2

Description
Control group:No Vitamin D will be administrated
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Dr Masoud Shayestehazar
Street address

Mazandaran University of Medical Sciences, Beginning of Valiasr Highway, Joybar three way

City
Sari

Province
Mazandaran

Postal code
۳۳۹۷۱-۴۸۱۵۷

Phone
+98 11 3304 4001

Email
mshayestehazar@mazums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mazandaran University of Medical Sciences

Full name of responsible person
Doctor Ahmad Ali Enayati

Street address
Deputy of Research and Technology of Mazandaran University of Medical Science, Moalem Sq., Moalem St., Sari

City
Sari

Province
Mazandaran

Postal code
۳۳۹۷۱-۴۸۱۵۷

Phone
+98 11 3337 7169

Email
mshayestehazar@mazums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Sari 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
Mazandaran University of Medical Sciences

Full name of responsible person
Doctor Masoud Shayesteh Azar

Position
Hip Surgery Fellowship

Latest degree
Subspecialist

Other areas of specialty/work
Orthopedics

Street address
Mazandaran University of Medical Sciences, First of Vali Asr high way., Joibar three way, Emam Sq., Sari

City
Sari

Province
Mazandaran

Postal code
4815733971

Phone
+98 11 3337 7169

Fax

Email
shayestehazar@mazums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mazandaran University of Medical Sciences

Full name of responsible person
Doctor Masoud Shayesteh Azar

Position
Hip Surgery Fellowship

Latest degree
Subspecialist

Other areas of specialty/work
Orthopedics

Street address
Mazandaran University of Medical Sciences, First of Vali Asr high way., Joibar three way, Emam Sq., Sari

City
Sari

Province
Mazandaran

Postal code
4815733971

Phone
+98 11 3337 7169

Fax

Email
shayestehazar@mazums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Mazandaran University of Medical Sciences

Full name of responsible person
Doctor Abolfazl Kazemi

Position
orthopedic resident

Latest degree

Medical doctor

Other areas of specialty/work

Orthopedics

Street address

Mazandaran University of Medical Sciences, First of Vali Asr high way., Joibar three way, Emam Sq., Sari

City

Sari

Province

Mazandaran

Postal code

4815733971

Phone

+98 11 3337 7169

Fax

Email

shayestehazar@mazums.ac.ir

Web page address

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

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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