

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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