

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 administered

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Imam Khomeini Hospital

**Full name of responsible person**

Dr Masoud Shayestehazar

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

**City**

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**Province**

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## 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**

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**Province**

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+98 11 3337 7169

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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  
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## Person responsible for scientific inquiries

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**Full name of responsible person**

Doctor Masoud Shayesteh Azar

**Position**

Hip Surgery Fellowship

**Latest degree**

Subspecialist

**Other areas of specialty/work**

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## 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

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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**

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