# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

28 May 2026

## The effect of vitamin D supplementation on inflammation and antioxidant markers in the burned hospitalized patients

### Protocol summary

**Study aim**
Effect of supplementation vitamin D3 on inflammatory and antioxidant factors in burnd patients

**Design**
A clinical trial with a control group with Two arms parallel-group randomized with Double blinding

**Settings and conduct**
In a double-blind controlled clinical trial study, 60 patients with 20% to 50% burn injuries referred to Imam Musa Kazem Medical Center and samples were randomly assigned to intervention and control groups. At the beginning of the study and before the intervention, demographic information and history of previous diseases will be obtained using the prepared questionnaires, as well as test results, patients' paraclinical procedures, as well as anthropometric measurements and food intake information from patients, will be done. This study is double-blind and the subjects will not know about the main supplement and placebo. Then, at the end of the study, fasting blood samples, anthropometric measurements, and nutritional information will be obtained from each patient again.

**Participants/Inclusion and exclusion criteria**
age range: 18-60, Patients with secondary degree burns with a burn level between 20-50%, Willing to participate in the study, not have a history of underlying diseases and other metabolic diseases, and not being pregnant or breastfeeding

**Intervention groups**
Pearl Vitamin D3 and Vitamin D3 placebo are designed for the control group.

**Main outcome variables**
Antioxidant markers, Inflammation markers

### General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20210116050044N1**
Registration date: **2021-03-08, 1399/12/18**
Registration timing: **registered_while_recruiting**

Last update: **2021-03-08, 1399/12/18**
Update count: **0**

**Registration date**
2021-03-08, 1399/12/18

**Registrant information**

**Name**
Fahimeh Beigi

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

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+98 31 3345 7670

**Email address**
f.beigi@mail.mui.ac.ir

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2021-01-20, 1399/11/01

**Expected recruitment end date**
2021-04-19, 1400/01/30

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
The effect of vitamin D supplementation on inflammation and antioxidant markers in the burned hospitalized patients

**Public title**

Effect of vitamin D in treatment of burn

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

people between the ages of 18-60 patients with secondary degree burns with a burn level between 20%-50% Vitamin D <30 ng/ml lack of supplementation vitamin D during the last three months No history underlying diseases including Kidney, Diabetes, hyperthyroidism and other metabolic diseases No pregnancy and breastfeeding

**Exclusion criteria:**

lack of cooperation participators with project facilitators during this study diagnosis of another chronic disease during this study Each patient can be excluded from the study at any stage if he/she is not satisfied with the study

**Age**

From **18 years** old to **60 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Care provider
- Data analyser
- Data and Safety Monitoring Board

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study, for random allocation, we used biased coin the method in individual randomization unit by a coin toss, and each person who was eligible for the study with flipping a coin divided into intervention group if it was headed and control group if it was tails

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

participants, principle investigators, physicians, nurses who care for participants during the trial, data collectors were unaware of the control and intervention groups

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Isfahan University of Medical Sciences

**Street address**

hezar jerib street

**City**

Isfahan

**Province**

Isfehan

**Postal code**

81746-73461

**Approval date**

2020-11-11, 1399/08/21

**Ethics committee reference number**

IR.MUI.MED.REC.1399.950

## Health conditions studied

### 1

**Description of health condition studied**

Burn of second degree of trunk, unspecified site

**ICD-10 code**

T21.20

**ICD-10 code description**

Burn of second degree of trunk, unspecified site

## Primary outcomes

### 1

**Description**

The amount of vitamin D through ELISA test is measured in ng/l

**Timepoint**

Measurement of vitamin D will be at the beginning of the study (before the intervention) and after the intervention

**Method of measurement**

The measure of variable is done by ELISA method.

## Secondary outcomes

### 1

**Description**

Inflammatory factor CRP is measured by photometric enriched turbidolatex method.

**Timepoint**

The variable is measured at the beginning of the study (before the intervention) and after the intervention at the end of the study.

**Method of measurement**

The measurement is done based on the CRP vial

### 2

**Description**

Antioxidant factors are measured in terms of ng / L based on ELISA method.

**Timepoint**

The variable is measured at the beginning of the study (before the intervention) and after the intervention at the

end of the study.

**Method of measurement**

The method of measuring antioxidant factors by ELISA kit.

## Intervention groups

### 1

**Description**

Intervention group: Vitamin D3 is produced in the form of a tablet with a dose of 2000 international units by Darsa Daru Pharmaceutical Company and is recommended for 8 weeks a day (one) at the same time with fatty foods.

**Category**

Treatment - Drugs

### 2

**Description**

Control group: vitamin D placebo is in the form of a pill with a dose of 2000 international units. To prepare a placebo, paraffin from Zahravi Pharmaceutical Company has been used and a placebo is recommended for 8 weeks a day (one) at the same time with the consumption of fatty foods.

**Category**

Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**
Isfahan university of medical sciences

**Full name of responsible person**
Fahimeh Beigi

**Street address**
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## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**
Esfahan University of Medical Sciences

**Full name of responsible person**
Vice-Chancellery for Research and Technology university

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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**
Esfahan 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**
Esfahan University of Medical Sciences

**Full name of responsible person**
Fahimeh Beigi

**Position**
Research expert

**Latest degree**
Ph.D.

**Other areas of specialty/work**
Molecular medicine

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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)**
No - There is not a plan to make this available
**Justification/reason for indecision/not sharing IPD**
Confidentiality of patient documents based on ethics in research
**Study Protocol**
Yes - There is a plan to make this available
**Statistical Analysis Plan**
No - There is not 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**
Yes - There is a plan to make this available
**Analytic Code**
No - There is not 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**
The effect of vitamin D supplementation on inflammation and antioxidant markers in the burned hospitalized patients. One of the most common deficiencies in the general population is vitamin D deficiency. This deficiency was present in more than 76% of critically ill patients, including burn patients.
**When the data will become available and for how long**
The data will become available on 1400/02/30 and the time of study takes three months.
**To whom data/document is available**
principle investigators, Co-workers, manuscript writers and research expert
**Under which criteria data/document could be used**
In order to scientific resources and under the conditions of citations
**From where data/document is obtainable**
comprehensive libarary system of medical university of Isfahan
**What processes are involved for a request to access data/document**
by researching of comprehensive libarary system of medical university of Isfahan
**Comments**