

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Evaluation of the effect of vitamin D3 supplementation in doses of 1000 and 3000 IU / day on hyperglycemic control, wound healing, wound infection and sepsis incidence and length of stay in hospital in burn patients

Protocol summary

Study aim

Evaluation of the effect of vitamin D3 supplementation in doses of 1000 and 3000 IU / day on hyperglycemic control, wound healing, wound infection and sepsis incidence and length of stay in hospital in burn patients

Design

Clinical trial with control group, blind, randomized, phase three on 54 patients. The crash was done using the computer software <https://www.sealedenvelope.com>.

Settings and conduct

With the cooperation of Ayatollah Taleghani Trauma and Burn Hospital in Ahvaz, the patients studied are selected from hospitalized in the age group of 18-50 years and from both sexes with a burn rate of 20-50%. On the one hand, it is done blindly, and the patients are those who are blind.

Participants/Inclusion and exclusion criteria

Age group 50-18 years _ Burns 50-20% - Second and third degree burns - At least two weeks in the hospital according to the doctor's prognosis Satisfaction of the individual Absence of chronic diseases such as diabetes and high blood pressure and chronic kidney disease No supplement with Vit D in the last 6 months Lack of disorders such as hypoparathyroidism, hyperthyroidism, tumors and bone disease Not receiving sex hormones to treat osteoporosis - Patient awareness and ability to answer questionnaire questions - Able to receive oral vitamin

Intervention groups

Group one: Receive a dose of 1000IU / day VitD3 Group Two: Receive a dose of 3000IU / day VitD3 Group three: Control group without supplement

Main outcome variables

Hyperglycemic control, wound healing, wound infection and sepsis, length of hospital stay

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200420047141N1**

Registration date: **2020-04-24, 1399/02/05**

Registration timing: **registered_while_recruiting**

Last update: **2020-04-24, 1399/02/05**

Update count: **0**

Registration date

2020-04-24, 1399/02/05

Registrant information

Name

elaheh ghadimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3337 1272

Email address

ghadimi.e@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-23, 1399/02/04

Expected recruitment end date

2020-06-19, 1399/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of vitamin D3 supplementation in doses of 1000 and 3000 IU / day on hyperglycemic control, wound healing, wound infection and sepsis incidence and length of stay in hospital in burn patients

Public title

Evaluation of the effect of vitamin D3 supplementation in doses of 1000 and 3000 IU / day on hyperglycemic control, wound healing, wound infection and sepsis incidence and length of stay in hospital in burn patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age group 50_18 years Burns 50-20% Second and third degree burns At least two weeks in the hospital according to the doctor's prognosis Satisfaction of the individual Absence of chronic diseases such as diabetes and high blood pressure and chronic kidney disease No supplement with Vit D in the last 6 months Lack of disorders such as hypoparathyroidism, hyperthyroidism, tumors and bone disease Not receiving sex hormones to treat osteoporosis Patient awareness and ability to answer questionnaire questions Able to receive oral vitamin

Exclusion criteria:

Diagnosis of the relevant physician and discretion to discontinue the supplement due to clinical problems created in the patient The patient's reluctance to continue studying Reduce awareness and ability to answer questionnaire questions The patient's death

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

<https://www.sealedenvelope.com> was used to randomly enter study participants. With the help of this site, for 54 participants in three defined groups A (group receiving 3000 IU of vitamin D daily), B (group receiving 1000 IU of vitamin D daily) and C (control group), the random order of entry in the study was determined.

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants enter the study with a personal satisfaction form and all study cases are explained to them. However, he does not know in which group and for what purpose he entered. Before starting the study, the patient will be told that he or she will not be provided

with any information.

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Jundishapur university of Medical Sciences

Street address

Golestan street, Arian1 building

City

Ahvaz

Province

Khouzestan

Postal code

6136753591

Approval date

2020-02-24, 1398/12/05

Ethics committee reference number

IR.AJUMS.REC.1398.907

Health conditions studied

1

Description of health condition studied

Burn patients

ICD-10 code

T30-2, T30

ICD-10 code description

Burn of second degree, body region unspecified, Burn of third degree, body region unspecified

Primary outcomes

1

Description

Hyperglycemic control

Timepoint

At least twice a week

Method of measurement

Blood sampling in fasting mode

2

Description

Wound healing

Timepoint

Before the start of the intervention, 7 days and 14 days after the intervention

Method of measurement

Bates-jensen Wound assessment tool

3

Description

Infection of the wound and sepsis

Timepoint

On the fifth day of hospitalization

Method of measurement

Biopsy of wound depth and blood culture

4

Description

The length of hospitalisation

Timepoint

From admission to discharge

Method of measurement

Count the number hospitalisation days

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The first group receives a dose of 1000IU vitamin D from Flexan on a daily basis and orally from the time of admission until discharge from the hospital.

Category

Prevention

2

Description

Intervention group: The second group receives a dose of 3000IU vitamin D from Flexan on a daily basis and orally from the time of admission until discharge from the hospital. (To access this dose, each patient will receive a 1000IU per l and a 2000IU per l per day.)

Category

Prevention

3

Description

Control group: No supplements

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Taleghani Trauma and Burn Hospital, Ahvaz

Full name of responsible person

Dr. Peyman Nejati

Street address

Khuzestan, Ahvaz, Padadshahr, The end of Hijrat Boulevard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad Badavi

Street address

Ahvaz Jundishapur University of Medical Science, Golestan highway

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Khuzestan

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6135715794

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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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Elaheh Ghadimi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

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Name of organization / entity

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Anahita Mansoori

Position

Assistant Professor

Latest degree

Ph.D.

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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

Due to the financial support of this research project carried out by Ahvaz Jundishapur University of Medical Sciences, it will be allowed to publish study data in the form of an article after the end of the intervention.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available