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-jensenWound 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 perl and a 2000IU perl 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
Khuozestan, Ahvaz, Padadshahr, The end of Hijrat Boulevard
City
Ahvaz
Province
Khouzestan
Postal code
6187954386
Phone
+98 61 3554 7996
Email
P.nejati97@gmail.com

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
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
+98 61 3336 5975
Email
itc@ajums.ac.ir
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

Street address
Gulestan, Arian1 Building

City
Ahvaz

Province
Khouzestan

Postal code
6136753591

Phone
+98 61 3337 1272

Email
ghadimi.elaheh1996@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Anahita Mansoori

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

Street address
Nutrition Department, Ahvaz Jundishapur University of Medical Science, Golestan highway

City
Ahvaz

Province
Khouzestan

Postal code
6135715794

Phone
+98 61 3336 2414

Email
mansoori-a@ajums.ac.ir

Person responsible for updating data

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

Street address
Golestan, Arian1 Building

City
Ahvaz

Province
Khouzestan

Postal code
6136753591

Phone
+98 61 3337 1272

Email
ghadimi.elaheh1996@gmail.com

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 Ahwaz 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