Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Acute effect of single high-dose vitamin D3 and the chronic effect of normal levels of 25-OHD on perioperative complications and clinical outcomes in brain tumor surgery patients

Protocol summary

Study aim

Determination of the acute effect of single high dose of vitamin D3 and chronic normal levels of vitamin D3 on surgical complications and clinical outcomes in patients undergoing brain tumor surgery

Design

Quasi-experimental study without randomization but with control group and sample size of 60 patients. This study is phase 3 and one-sided blind

Settings and conduct

The present study will conduct on 60 patients with inclusion criteria hoapitalized in ShohadaTajrish hospital . Based on serum levels of 25OHD , patients will be divided into intervention group (≤ 20) and control group (more than 30). After preparing the results of vitamin D, albumin, phosphorus and calcium tests, patients with deficiency and without hypercalcemia or hyperphosphatemia will receive 300,000 units of vitamin D in the form of intramuscular injection. The changes in these markers will be determined on the 5th day postop in the intervention group. The incidence of complications and clinical outcomes intra and post surgery, mortality in one and six months in both groups will be compared.

Participants/Inclusion and exclusion criteria

The willingness to cooperate and complete the informed consent Age of patients ≥ 18 Definitive diagnosis of brain tumor and need craniotomy for resection Levels of 25-OHD ≤ 20 ng/mL for intervention group Levels of 25-OHD > 30 ng/mL for normal group ; Unwillingness to co-operate Participation in other clinical trials Pregnancy and lactation Hypercalcemia Hyperphosphatemia

Intervention groups

Intervention group: The group with a serum level of vitamin D 3 less than 20 ng / mL. Intervention as intramuscular injection of a single dose of vitamin D contains 300,000 units of vitamin D. Control group: normal serum levels of vitamin D3 (greater than 30)

Main outcome variables

Changes in serum levels of 25OHD before and after injection and surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190126042496N1**
Registration date: **2019-07-24, 1398/05/02**
Registration timing: **registered_while_recruiting**

Last update: **2019-07-24, 1398/05/02**
Update count: **0**

Registration date

2019-07-24, 1398/05/02

Registrant information

Name

Mohammadrez Shahmohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-06, 1398/01/17

Expected recruitment end date

2019-10-08, 1398/07/16

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Acute effect of single high-dose vitamin D3 and the chronic effect of normal levels of 25-OHD on perioperative complications and clinical outcomes in brain tumor surgery patients

Public title
Effect of vitamin D in enhanced recovery after brain surgery
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
The willingness to cooperate and complete the informed consent form by the patient or legal surrogate The patient's age ≥ 18 Definitive diagnosis of brain tumor and need craniotomy for resection Levels of 25-OHD ≤ 20 ng/mL for intervention group Levels of 25-OHD > 30 ng/mL for normal group
Exclusion criteria:
Unwillingness to co-operate by the patients or their surrogate at the beginning of the study Participation in other clinical trials at the same time with this study Pregnancy and lactation Hypercalcemia Hyperphosphatemia Tuberculosis Sarcoidosis History of nephrolithiasis
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **60**
More than 1 sample in each individual
Number of samples in each individual: **1**
Each sample is a patient with a brain tumor undergoing craniotomy surgery
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
For participants, supplemental vitamin D Injection will be described to enhance and improve the health status and will be included in the study if they are satisfied. However, since this injection will be performed between nurses' routine treatments in patients, the patient will not be aware of the timing of receiving the vitamin and its type.
Placebo
Not used
Assignment
Parallel
Other design features
This study is a Quasi-experimental study in which randomization is not applicable. A group with vitamin D deficiency will receive vitamin D , and there will be no intervention on the group with normal serum levels. The two groups will be compared in terms of post-surgical outcomes

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Institutional Research Ethics Committee - Shahid Beheshti University of Medical Sciences
Street address
3rth floor, Faculty of Medicine, next to Taleghani Hospital, Evin, Shahid Chamran Highway
City
Tehran
Province
Tehran
Postal code
1985717434 - 1939547
Approval date
2018-06-17, 1397/03/27
Ethics committee reference number
IR.SBMU.RETECH.REC.1397.271

Health conditions studied

1

Description of health condition studied
Patients with brain tumors who have candidate for craniotomy surgery
ICD-10 code
C71
ICD-10 code description
Malignant neoplasm of brain

Primary outcomes

1

Description
Changes in serum levels of 25OHD before and after injection and surgery
Timepoint
Measurement of serum levels of 25OHD at the beginning of the study in all patients. Measurement of serum levels of 25OHD on the fifth day after surgery in intervention group who received a single high dose of vitamin D prior to surgery
Method of measurement
Laboratory measurements of 25OHD serum levels using

Monobind kit by Enzyme-Linked Immunosorbent Assay (ELISA) method

Secondary outcomes

1

Description
Intraoperative Active Bleeding
Timepoint
During surgery time
Method of measurement
Amount of blood loss (cc) during surgery based on estimation of anesthesiologist

2

Description
Incidence of ventricular fibrillation (VF) during surgery
Timepoint
During surgery time
Method of measurement
Based on doctor's diagnosis

3

Description
Incidence of cardiac arrest during surgery
Timepoint
During surgery time
Method of measurement
Based on doctor's diagnosis

4

Description
Incidence of severe bradycardia during surgery
Timepoint
During surgery time
Method of measurement
Based on doctor's diagnosis

5

Description
Incidence of hypotension during surgery
Timepoint
During surgery time
Method of measurement
Based on doctor's diagnosis

6

Description
Incidence of hypertension during surgery
Timepoint
During surgery time
Method of measurement
Based on doctor's diagnosis

7

Description
Incidence of intracranial hematoma after surgery
Timepoint
Immediately after surgery until the end of the hospitalization period for each patient (up to 1 month after surgery)
Method of measurement
Based on doctor's diagnosis, computerized tomography (CT) scan, Magnetic resonance imaging (MRI)

8

Description
Incidence of cerebral edema after surgery
Timepoint
Immediately after surgery until the end of the hospitalization period for each patient (up to 1 month after surgery)
Method of measurement
Based on doctor's diagnosis, computerized tomography (CT) scan, Magnetic resonance imaging (MRI)

9

Description
Incidence of seizure after surgery
Timepoint
Immediately after surgery until the end of the hospitalization period for each patient (up to 1 month after surgery)
Method of measurement
Based on doctor's diagnosis

10

Description
Incidence of Myocardial Infarction (MI) after surgery
Timepoint
Immediately after surgery until the end of the hospitalization period for each patient (up to 1 month after surgery)
Method of measurement
Based on doctor's diagnosis

11

Description
Incidence of Deep Vain Thrombosis (DVT) after surgery
Timepoint
Immediately after surgery until the end of the hospitalization period for each patient (up to 1 month after surgery)
Method of measurement
Based on doctor's diagnosis

12

Description
Incidence of Pulmonary Embolism (PE) after surgery
Timepoint
Immediately after surgery until the end of the hospitalization period for each patient (up to 1 month after surgery)
Method of measurement

Based on doctor's diagnosis

13

Description
Incidence of meningitis after surgery
Timepoint
Immediately after surgery until the end of the hospitalization period for each patient (up to 1 month after surgery)
Method of measurement
Based on doctor's diagnosis

14

Description
Incidence of postoperative wound infection
Timepoint
Immediately after surgery until the end of the hospitalization period for each patient (up to 1 month after surgery)
Method of measurement
Based on doctor's diagnosis

15

Description
Incidence of Sepsis after surgery
Timepoint
Immediately after surgery until the end of the hospitalization period for each patient (up to 1 month after surgery)
Method of measurement
Based on doctor's diagnosis

16

Description
Length of stay in intensive care unit (ICU)
Timepoint
The number of days after surgery from the time of arrival in the ICU until the discharge from there
Method of measurement
Number of days staying in ICU with reference to medical records

17

Description
Duration of hospitalization
Timepoint
Total number of hospital admission days
Method of measurement
Number of days staying in hospital with reference to medical records

18

Description
Mortality rate during a month
Timepoint
Immediately after surgery until one month later
Method of measurement
According to the hospital documents as well as the telephone question of the patient or his surrogate

19

Description
Mortality rate during six months
Timepoint
Immediately after surgery until six months later
Method of measurement
Telephone interview with the patient or his surrogate

Intervention groups

1

Description
Intervention group: A group of patients with the serum level of 25OHD ≤ 20 who are known that vitamin D deficiency. The injection of a single dose of vitamin D contains 300,000 units of vitamin D, which will be administered as a single intramuscular injection by a nurse to each patient before surgery.
Category
Treatment - Other

2

Description
Control group: patients with normal serum levels of vitamin d (25OHD >30), without any intervention.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shohada-e-Tajrish hospital
Full name of responsible person
Mohammadreza shahmohammadi
Street address
Shohada-e-Tajrish hospital, Tajrish Square, Tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity

Neurofunctional Reseach Center of Shohada Tajrish Hospital

Full name of responsible person

Prof. Dr. Afshin Zarghi

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Neurofunctional Reseach Center of Shohada Tajrish Hospital, Tajrish Square, Tehran, Iran

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Phone

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Email

neurofunctional.cntr@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Neurofunctional Reseach Center of Shohada Tajrish Hospital

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mohammadreza shahmohammadi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

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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)

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