Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jul 2026

The Study of Vitamin D supplementation`s effect in the treatment of Helicobacter pylori eradication in patients with dyspepsia

Protocol summary

Study aim
Determination of the Effect of Vitamin D Supplementation on Helicobacter Pylori Infection

Design
Control and intervention group, community based and pragmatic, with parallel groups, blind, randomized

Settings and conduct
All patients over 18 years who referred to Ziaeian Hospital clinics with positive fecal antigen test or RUT for Helicobacter pylori, are informed after obtaining informed consent and examining exclusion criteria.At the beginning, oral vitamin D was administered as 50000 units weekly to the intervention group (60 patients) and placebo weekly to the control group (60 patients) for 12 weeks. Six weeks after the start, the anti-inflammatory drug Helicobacter pylori (PPI Amoxicillin-Tinidazole and levoxin). Six weeks after the completion of the antibiotic regimen in both groups, they were subjected to fecal antigen test for the detection of HP eradication.

Participants/Inclusion and exclusion criteria
-

Intervention groups
The intervention group includes people 18 years old and older who receive pills of Vitamin D with a dose of 50000 for 3 months.This drug should be taken weekly. The control group includes those 18 years old and older who receive placebo.

Main outcome variables
Determining the Effect of Vitamin D Supplementation on Helicobacter Pylori Infection

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180922041089N2**
Registration date: **2019-02-06, 1397/11/17**
Registration timing: **registered_while_recruiting**
Last update: **2019-02-06, 1397/11/17**
Update count: **0**

Registration date
2019-02-06, 1397/11/17

Registrant information

Name
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Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-10-23, 1397/08/01

Expected recruitment end date
2019-04-21, 1398/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Study of Vitamin D supplementation`s effect in the treatment of Helicobacter pylori eradication in patients with dyspepsia

Public title
The Study of Vitamin D Supplement-aid in the treatment of Helicobacter Pylori eradication

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 18 years A test of the fecal antigen of the Helicobacter pylori or Rapid urease test (RUT) is positive All patients with functional dyspepsia of the pseudo-ulcer type who did not respond to (or recurring) acid reflux therapy, or the presence or history of gastric or duodenal peptic ulcer in a patient or first-degree relatives of patients with gastric cancer Informed consent Form

Exclusion criteria:

The history of epilepsy History of chronic diseases (CHB, CKD, COPD, recurrent CVA or dementia, liver cirrhosis) Patients own cancers Severe psychiatric illnesses such as schizophrenia, major depression, bipolar disorders History of antibiotic use in the last 6 weeks Patients with dyspepsia with a predominant symptom of reflux Drug, alcohol and cigarettes History of gastric surgeries, IBD, diabetes, pathological weight loss (weight loss over 10% of body weight over the past 6 months) Anemia (Hemoglobin in men under 14 in males under 11 and in menopausal women under 12 (1)) Diabetes (if FBS is greater than or equal to 126 or HbA1c greater than or equal to 6.5%) corticosteroids use in the last 3 months Use of vitamin D supplements with therapeutic doses during the last 3 months or during the study Participate in another research project over the past 3 months Pregnancy or breastfeeding History of H pylori infection treatment in the past History of kidney stones Participants' unwillingness to take medication or placebo History of any allergy or side effects BMI greater than 40

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

A random allocation method will be used. There are 30 green cards (interventions) and 30 orange cards (controls) inside white envelopes for women and the same number for men and placed inside two separate lottery boxes and eligible for each patient randomly and with Pay attention to the gender of a card.

Blinding (investigator's opinion)

Double blinded

Blinding description

To eliminate the bias caused by the patient's or doctor's knowledge of the type of treatment received and its possible effect on the outcome of the study, the study is done in two blind ways. Given that the vitamin D and placebo tablets are placed in the same full capsule. The patient and the assessing doctor are not aware of the type of medication received.

Placebo

Used

Assignment

Parallel

Other design features

-Sampling method of this study is simple random sampling, so that the selected units have equal chance to be selected. Select either through the lottery or through the use of random numbers table. We will use the lottery method so that we will have two boxes for our execution, and will be used in two colors. The green color for the intervention group and the orange color for the control group are considered. 30 green paper, 30 orange paper for women in a box and 30 green paper, 30 orange paper for men in another box. The doctor gives a sheet to each patient that has criteria for entry provided there is no exit criteria. The patient is referred for further investigation to a questionnaire who is not known about the presence of the patient in the control group or intervention. after the patient is confirmed by the other criteria on the basis of other criteria, is confirmed in terms of the presence of symptoms. For each patient, demographic information and MNA questionnaire are completed. The height and weight of individuals are also measured.The height of the people is measured in the form of standing, without shoes and with a wall hanging seka in cm.The weight of people with a minimum of clothes and without shoes and heavy accessories such as cell phones and bags, is measured with a scalable scale in kilograms and a precision of 500 grams.And finally referred to the doctor for a free visit.At the start of the study each patient is given a vitamin D supplement (Zahravi Company) on a weekly basis of 50,000 units and placebo is given to control group for 12 weeks (3 months).Six weeks after the start of the project, the patients were re-examined to receive a 5-day antibiotic regimen of Anti-Helicobacter pylori (PPI and amoxicillin and tinidazole and levofloxacin). At the same time, the intervention group are evaluated about the toxicity of serum vitamin D level and patients with serum vitamin D level above 100 are excluded from the study. Patients who do not follow this diet for any reason (antibiotic complications, intolerance of the drug ...) are excluded.After 3 months from oral administration of vitamin D or about 6 weeks after the completion of the anti-hereditary bacterial diet in patients, , each of the two groups is subjected to the challenge of helicobacter pylori eradication through a fecal hollybucher pylori test (UBT Urea Breath Test). Also, the clinical symptoms of patients are recorded in each of the two groups and due to these symptoms, they are interviewed and examined.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

National Ethics Committee for Biomedical Research

Street address
Ziaeian Hospital,Abuzar Street,Tehran Town
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1366736511
Approval date
2018-08-25, 1397/06/03
Ethics committee reference number
IR.TUMS.DDRI.REC.1397.003

Health conditions studied

1

Description of health condition studied
Dyspepsia due to Helicobacterpylori
ICD-10 code
K30
ICD-10 code description
Functional dyspepsia

Primary outcomes

1

Description
H-pylori Infection
Timepoint
At the beginning of the study before the intervention and 4 months after taking oral vitamin D
Method of measurement
Stool-Antigen test Or RUT

Secondary outcomes

1

Description
Bloating
Timepoint
At the beginning of the study and after 4 months
Method of measurement
Questionnaire and self-declaration

2

Description
nausea and vomiting
Timepoint
At the beginning of the study and after 4 months
Method of measurement
Questionnaire and self-declaration

3

Description
Abdominal pain
Timepoint
At the beginning of the study and after 4 months
Method of measurement
Questionnaire and self-declaration

Intervention groups

1

Description
The intervention group includes people 18 years old and older who receive pills of Vitamin D with a dose of 50000 for 3 months.This drug should be taken weekly.
Category
Treatment - Drugs

2

Description
The control group includes those 18 years old and older who receive placebo.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

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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
Tehran 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

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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