Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of vitamin B5 administration compared to placebo on stress; depression; Anxiety, oxidative stress level and serum cortisol level in type 2 diabetes patients

Protocol summary

Study aim
Determining the effect of vitamin B5 administration on stress; depression; anxiety, oxidative stress level and cortisol level in patients with type 2 diabetes

Design
Clinical trial with a control group, double-blind, randomized, phase 2 on 48 patients. The randomized treatment allocation sequence will be generated by the statistical consultant using a table of random numbers.

Settings and conduct
The current clinical trial study will be conducted on 48 patients with type 2 diabetes referred to the Imam Ali clinic in Shahrekord. After the diagnosis of type 2 diabetes and stress, anxiety, or depression, their cortisol level will be evaluated. Then, for two months, they will be given vitamin B5 tablets (250 mg) or a placebo in a blinded manner, and the status of the investigated parameters will be checked at the end of the two months.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age between 30-65 years; not taking oral contraceptives in the last month; non-smokers; People who have not received vitamin B supplements at least 3 months before the study; People who are not professional athletes. Exclusion criteria: non-cooperation of patients to participate in the study; the presence of congenital anxiety diseases; incomplete completion of the questionnaire; People taking combined oral blood sugar-lowering drugs such as Sinuripa tablets; People taking drugs related to severe depression (bipolar); People taking vitamin B5 supplements before starting the tests

Intervention groups
The intervention group: will receive vitamin B5 chewable tablets along with metformin/insulin. The control group: the group of diabetic patients who will receive metformin/insulin along with placebo.

Main outcome variables
Average score of depression; Average score of anxiety; Average score of stress

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230702058641N2**
Registration date: **2024-02-01, 1402/11/12**
Registration timing: **registered_while_recruiting**

Last update: **2024-09-21, 1403/06/31**
Update count: **1**

Registration date
2024-02-01, 1402/11/12

Registrant information

Name
Reihaneh Sadeghian

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-01-20, 1402/10/30

Expected recruitment end date
2024-03-20, 1403/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of vitamin B5 administration compared to placebo on stress; depression; Anxiety, oxidative stress level and serum cortisol level in type 2 diabetes patients

Public title
The effect of vitamin B5 on stress; depression and anxiety
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 30-65 years People who are not professional athletes. Receiving metformin/insulin. Patients should not take melatonin, aspirin, D3, omega3 during the study period. Not taking oral contraceptives in the last month people who have not received vitamin B supplements at least 3 months before the study.
Exclusion criteria:
Non-cooperation of patients to participate in the study Use of corticosteroids and anticoagulants in the last month Smokers The existence of congenital cognitive and anxiety diseases Incomplete completion of the questionnaire People taking combined oral hypoglycemic drugs such as Sinuripa tablets People taking drugs related to severe depression (bipolar) People taking vitamin B5 supplements before starting the tests
Age
From **30 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **48**
Randomization (investigator's opinion)
Randomized
Randomization description
Diabetic patients are randomly divided into two groups "control and intervention" after examination and if they meet the criteria to enter the plan. By using online sites for random allocation, random block method with blocks of 4 will be used. For the random sequence, a numerical code will be defined and people will receive the numerical code in the same order as they enter and will be placed in groups according to the block.
Blinding (investigator's opinion)
Double blinded
Blinding description
Double-blind (researcher and patients do not know which person is assigned to which treatment group). Patients were also blinded according to the received intervention, which is the use of tablets with the same shape, taste, and color.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shahrekord University of Medical Sciences
Street address
Headquarters of Shahrekord University of Medical Sciencesl; Kashani Street
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8816758915
Approval date
2023-11-21, 1402/08/30
Ethics committee reference number
IR.SKUMS.MED.REC.1402.063

Health conditions studied

1

Description of health condition studied
Type 2 diabetes
ICD-10 code
E11
ICD-10 code description
Type 2 diabetes mellitus

Primary outcomes

1

Description
Score of depression
Timepoint
At the beginning of the study and after two months after taking vitamin B5 or placebo
Method of measurement
DASS-21 Scale

2

Description
Score of anxiety
Timepoint
At the beginning of the study and after two months after taking vitamin B5 or placebo

Method of measurement
DASS-21 Scale

3

Description
Score of stress
Timepoint
At the beginning of the study and after two months after taking vitamin B5 or placebo
Method of measurement
DASS-21 Scale

Secondary outcomes

1

Description
Cortisol level
Timepoint
At the beginning of the study and after two months
Method of measurement
ELISA technique

2

Description
Nitric oxide levels
Timepoint
At the beginning of the study and after two months
Method of measurement
Gress method

3

Description
Malondialdehyde level
Timepoint
At the beginning of the study and after two months
Method of measurement
Thiobarbituric acid method

4

Description
Antioxidant capacity
Timepoint
At the beginning of the study and after two months
Method of measurement
FRAP measurement

Intervention groups

1

Description
Intervention group: vitamin B5 chewable tablet with a dose of 250 mg (produced by Shehab Pharmaceutical Company) once a day, which will be given to them along with metformin/insulin for 8 weeks.
Category
Treatment - Drugs

2

Description
Control group: Placebo along with metformin/insulin will be given to them for 8 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Ali Clinic; Shahrekord University of Medical Sciences
Full name of responsible person
Reihaneh Sadeghian
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Imam Ali (A.S.) Specialized Clinic; Shariati Blvd.; Shahrekord
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Golshan Taghipour
Street address
Clinic No. 1 of Hajar Hospital; Parastar street; Shahrekord
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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
Shahre-kord 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
Shahre-kord University of Medical Sciences

Full name of responsible person
Reihaneh Sadeghian

Position
Assistant Professor of physiology

Latest degree
Ph.D.

Other areas of specialty/work
Physiology

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Person responsible for updating data

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https://www.researchgate.net/scientific-contributions/Motahareh-Sadat-Mirhaj-Mohammadabadi-2198157046

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is 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
All data is potentially shareable after de-identifying individuals

When the data will become available and for how long
The access period starts 6 months after the results are published

To whom data/document is available

It will be available for researchers working in academic and scientific institutions

Under which criteria data/document could be used

The data can be used after obtaining permission from both supervisors

From where data/document is obtainable

Reihane Sadeghian; Adress: University Headquarters; Kashani Blvd.; Shahrekord. Postal code: 8815713471. Phone number: 038-0333061-5-3333061; Email: reihaneh.sadeghian5@gmail.com

What processes are involved for a request to access data/document

The data can be accessed after the official letter from the Research and Technology Vice-Chancellor of the relevant university.

Comments

Trial results

Please tick if results have been published

Yes

Summary result posting date

2024-09-21, 1403/06/31

Table of baseline comparison

Variable		Group		
		Control.N=19	intervention.N=19	p-value
Frequency (Percentage)				
Gender	male	9(47.4)	7(36.8)	0.511
	female	10(52.6)	12(63.2)	
Marital status	Single	0(0)	0(0)	1.000
	marreid	19(100)	(100)19	
Blood sugar lowering drug	Metformin	11(57.9)	15(78.9)	0.163
	Insulin	8(42.1)	4(21.1)	
Family History	1st degree family	0(0.0)	0(0.0)	
	2nd degree family	(100)19	(100)19	1.000
	No record	0(0.0)	0(0.0)	
Level of Education	Illiterate	7(36.8)	6(31.6)	0.723
	Primary education	7(36.8)	9(47.4)	
	Secondary education	4(21.1)	2(10.5)	
	Bachelor 's degree and above	1(5.3)	2(10.5)	
Average ± Standard Deviation				
Age (years)		56.94 ±9.11	55.21±3.45	0.445
Body mass index (BMI)		27.47 ±2.58	29.35±1.63	0.076
Fasting blood sugar (FBS)		142.89±42.58	154.26 ±26.97	0.333
B5 Vitamin nutritional status		97.5±30.1	91.4±56.0	0.095
Trait anxiety		48.21±5.88	48.53±6.23	0.873
Situational anxiety		48.47±3.38	49.37±5.13	0.530
General health		18.32±1.11	18.37±1.16	0.887
Physical performance		23.00±2.19	24.84±2.34	0.017
Limitation due to physical health condition		15.11±2.26	14.21±2.68	0.273

Limitation caused by emotional health status		11.42±2.19	11.16±3.24	0.771
Energy and vitality		10.79±1.51	10.74±1.51	0.911
Emotional health		16.37±1.74	17.05±2.72	0.361
Social performance		6.05±0.85	6.21±1.27	0.655
Pain		6.21±1.51	5.95±1.99	0.649
Cortisol levels		6.19±1.96	8.37 ±3.37	0.020
Middle (first and third quadrants)				
Depression, Anxiety, Stress (DASS-21)		16 (10-30)	14 (8-24)	0.704
Beck Anxiety Inventory (BAI)		9 (3-11)	8 (4-15)	0.520

Participant flow diagram

Reihaneh Sadeghian	Supervisor
Seyed Hasan Hosseini	MD student
Golshan Taghipour	Supervisor
Motahareh Sadat Mirhaj	*Advisor*
Ammar Salehi	*Advisor*
Mahboobe Taghipour	*Scientific Co-Workers*
Alireza Amirbeigi	*Scientific Co-Workers*

Table of variable outcomes' results

	control			intervention			difference		
variables	before	after	p-value	before	after	p-value	control	internention	p-value
Body mass index (BMI)	27.47±2.58	27.51±2.57	0.217	29.35±1.63	29.40±1.57	0.488	0.04±0.13	0.05±0.23	0.844
Fasting blood sugar (FBS)	142.89±42.58	142±41.70	0.601	154.26±26.97	148.42±12.44	0.251	-0.89±7.33	-5.84±21.47	0.352
B5 Vitamin nutritional status	5.97±1.30	5.83±1.29	0.164	4.91±0.56	4.97±0.51	0.202	0.14±0.41	0.06±0.19	0.073
Trait anxiety	48.21±5.88	49.11±5.85	0.056	48.53±6.23	46.89±6.80	0.047	0.89±1.91	-1.63±3.74	0.014
Situational anxiety	48.47±3.39	48.95±3.70	0.432	49.37±5.13	46.42±5.26	0.002	0.47±2.57	-2.95±3.50	0.002
General health	18.32±1.11	18.37±1.42	0.790	18.37±1.16	18.05±1.68	0.187	0.05±0.85	-0.32±1.00	0.229
Physical performance	23.00±2.19	23.72±2.22	0.007	24.84±2.34	25.68±3.00	0.145	0.42±0.61	0.84±2.41	0.469
Limitation due to physical health condition	15.11±2.26	14.68±2.31	0.002	14.21±2.68	14.53±3.15	0.055	-0.42±0.51	0.32±0.67	0.001
Limitation caused by emotional health status	11.42±2.19	11.68±2.45	0.056	11.16±3.24	12.42±2.83	<0.001	0.26±0.56	1.26±1.15	0.002
Energy and vitality	10.79±1.151	11.16±1.64	0.005	10.47±1.37	11.00±1.89	0.471	0.37±0.50	0.26±1.56	0.782
Emotional health	16.37±1.74	16.37±1.74	1.000	17.05±2.72	17.58±3.08	0.249	0.00±0.82	0.53±1.93	0.280
Social performance	6.05±0.85	6.21±1.51	0.083	6.21±1.27	6.47±1.26	0.056	0.16±0.37	0.26±0.56	0.501

Pain	6.21±1.51	5.79±1.44	0.002	5.95±1.99	5.53±2.41	0.119	-0.42±0.51	-0.42±1.12	1.000
Cortisol levels	6.19±1.96	6.37±2.02	0.211	8.37±3.37	6.12±2.57	0.042	0.18±0.60	-2.25±4.48	0.031
Depression, Anxiety, Stress (DASS-21)	16 (10-30)	16 (10-28)	0.042	14 (8-24)	7 (6-13)	0.003	0 (-2-0)	-5 (-10-1)	<0.001
Beck Anxiety Inventory (BAI)	9 (3-11)	7 (3-10)	0.047	8 (4-15)	6 (4-13)	<0.001	-1 (-2-0)	-1 (-4-0)	0.235

Table of adverse events

First publication date

empty

Abstract of published paper

There have been limited research on the impact of a particular dietary pattern, like consuming pantothenic acid, on the emergence of stress, anxiety, and depression during diabetes induction. According to this issue, this study was designed. The study involved 38 patients aged 30–65 with type 2 diabetes, divided into two groups receiving vitamin B5 and a control group. The intervention group received 250 mg of vitamin B5 tablets for two months, and stress, anxiety, and depression parameters and the level of cortisol were measured at the start and end of the study. The results showed that in the intervention group, situational anxiety (P<0.01), cortisol level (P<0.05), depression score (P<0.01), and anxiety score of Dass-21 (P = 0.001) after the intervention were significantly lower than before the intervention. The difference (after-before) between trait anxiety (P<0.05), situational anxiety (P = 0.002), and anxiety score (P<0.001) in the intervention group was significantly lower than the control group. Also, the difference (after-before) in the limitation due to physical health status (P = 0.001), limitation due to emotional health status (P = 0.002), and cortisol level (P = 0.031) in the intervention group was significantly higher than the control group. Vitamin B5 supplementation may reduce depression and cortisol levels in type 2 diabetes patients but doesn't affect anxiety, highlighting the need for future studies to understand its role.