

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 May 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)

##### Phone

+98 915 205 8035

##### Email address

reihaneh.sadeghian5@gmail.com

##### 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 Sciences; 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

#### Street address

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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<https://imamaliclinic.skums.ac.ir/>

### 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**  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

### Contact

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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

variables	control			intervention			difference		
	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.