Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Evaluation of therapeutic effects of lactocare® probiotic on clinical symptoms, frequency of T cell subsets and expression of HOTAIR and MEG3 genes in patients with type II diabetes in comparison with control group

Protocol summary

Study aim

Determining the effect of lactocare probiotic drug on TH1, TH2, TH17 and Treg cells in patients with type 2 diabetes comparing with the placebo group; Determining and comparing the the level of CHOL, LDL, HDL, TG, FBS and the expression level of HOTAIR and MEG3 genes in the study groups before and after the intervention.

Design

Clinical trial with a control group, with parallel groups, double-blind, randomized block permutation, phase 2 on 80 patients. R software version 4.0.2 will be used for randomization.

Settings and conduct

Patients selection will be done in the diabetes clinic of Bo Ali Hospital in Zahedan will be done with the opinion of an internist or endocrinologist. After random allocation, the first group will receive lactocare probiotic and the second group will receive placebo. In each groups, desired variables (real time PCR expression of the desired genes and flow cytometry of T cells and enzymatic assay of fasting blood sugar and fat profile) will be examined before and after the intervention and finally a comparison between the two groups will be done. In this research, a double-blind method will be used, so that the participants, the person responsible for providing the drugs and the person responsible for recording the results (laboratory expert), will not be aware of the intervention type.

Participants/Inclusion and exclusion criteria

All patients with type 2 diabetes referred to the diabetes clinic of Bo Ali Hospital in Zahedan, who are identified and treated by an internist or endocrinologist.

Intervention groups

One lactocare probiotic capsule will be applied daily for 90 days in the intervention group and placebo in the control group.

Main outcome variables

Changes in T cells population, differences in gene expression, changes in clinical symptoms in patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220727055564N1**
Registration date: **2022-08-04, 1401/05/13**
Registration timing: **prospective**

Last update: **2022-08-04, 1401/05/13**
Update count: **0**

Registration date

2022-08-04, 1401/05/13

Registrant information

Name

Mahdi Atabaki

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3323 2545

Email address

atabaki80@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-23, 1401/08/01

Expected recruitment end date

2023-01-21, 1401/11/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of therapeutic effects of lactocare® probiotic on clinical symptoms, frequency of T cell subsets and expression of HOTAIR and MEG3 genes in patients with type II diabetes in comparison with control group

Public title
Evaluation of Lactocare probiotic effects on the immune system in patients with type II diabetes
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having a willingness and informed consent to participate in the study Having clinical symptoms of type 2 diabetes Confirmation of type 2 diabetes based on clinical symptoms and diagnostic tests by a specialist doctor No recent history of inflammatory diseases No history of receiving anti-inflammatory drugs No history of taking corticosteroid drugs Absence of immune system diseases and immune deficiencies
Exclusion criteria:
History of heart diseases including: blood pressure, heart failure, heart attack in the last month History of autoimmune diseases including: type 1 diabetes, multiple sclerosis, MS, lupus erythematosus, various types of vasculitis, rheumatism, Crohn's disease, etc. History of liver diseases including: liver cirrhosis and hepatitis in the past year History of underlying lung diseases such as: asthma, bronchiolitis, respiratory allergies, bronchiectasis, COPD History of organ transplant in the last three months People with a history of alcohol consumption Taking immunosuppressive drugs
Age
No age limit
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Random assignment of patients to two groups will be done by permuted block stratified randomization method. In this way, eligible referring patients are classified according to the age and gender in order of entry. Then, they are assigned to the desired group based on 2-blocks (consisting of two groups A and B) that are randomly selected from among all the possible states of permutations. These blocks were created using R software version 4.0.2.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this research, the double-blind method will be used. So that the participants, the person responsible for providing the drug or placebo and the person responsible for recording the results (laboratory expert) will not be aware of the intervention type. In this trial, the intervention group will receive lactocare probiotic and the control group will receive the placebo, and patients will not be informed to which group they have been assigned.
Placebo
Used
Assignment
Parallel
Other design features
In this study, the expression level of HOTAIR and MEG3 genes as well as the flow cytometry of T Helper-1, T Helper-2, T Helper-17 and Treg cells before and after the intervention (daily consumption of lactocare probiotic and placebo) will be investigated.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Zahedan University of Medical Sciences
Street address
Campus of Zahedan University of Medical Sciences, Dr. Hesabi Square, Zahedan, Iran
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Approval date
2022-07-27, 1401/05/05
Ethics committee reference number
IR.ZAUMS.REC.1401.150

Health conditions studied

1

Description of health condition studied
type 2 diabetes
ICD-10 code
E11.9
ICD-10 code description

Type 2 diabetes without complications

Primary outcomes

1

Description
Frequency of T helper 1 cell population
Timepoint
Measuring the frequency of T helper 1 cells at the beginning of the study (before the start of the intervention) and 3 months after the start of lactocare probiotic or placebo
Method of measurement
T Helper 1 is the main cell in inflammatory responses and produces interferon-gamma, which is measured by flow cytometry.

2

Description
Frequency of T helper 2 cell population
Timepoint
Measuring the frequency of T helper2 cells at the beginning of the study (before the start of the intervention) and 3 months after the start of lactocare probiotic or placebo
Method of measurement
T helper 2 is the main cell in the protection of inflammatory responses and the producer of interleukin 4, which is measured by flow cytometry

3

Description
Frequency of T helper cell population 17
Timepoint
Measuring the frequency of T helper 17 cells at the beginning of the study (before the start of the intervention) and 3 months after the start of lactocare probiotic or placebo
Method of measurement
T Helper 17 is a cell effective in inflammatory responses and produces interleukin 17, which is measured by flow cytometry.

4

Description
Frequency of regulatory T cell population
Timepoint
Measurement of the frequency of regulatory T cells at the beginning of the study (before the start of the intervention) and 3 months after the start of lactocare probiotic or placebo
Method of measurement
Regulatory T, a cell effective in protecting inflammatory responses, with foxp3 factor measured by flow cytometry.

5

Description
Maternal expressed gene 3 (lnc-MEG3)
Timepoint
Measurement of the lnc-MEG3 gene expression level at the beginning of the study (before the start of the intervention) and 3 months after the start of taking lactocare probiotic drug or placebo.
Method of measurement
Investigating the expression level of lnc-MEG3, which is an LncRNA that affects the functions of the immune system, compared to U6 small nuclear 1 is measured by real time PCR method.

6

Description
Gene Expression (lnc-HOTAIR) HOX Transcript Antisense RNA
Timepoint
Measurement of the lnc-HOTAIR gene expression level at the beginning of the study (before the start of the intervention) and 3 months after the start of taking lactocare probiotic drug or placebo
Method of measurement
Investigating the level of expression of lnc-HOTAIR, which is an LncRNA that affects the functions of the immune system, compared to U6 small nuclear 1, is measured by real time PCR method.

7

Description
FBS(fasting blood glucose)
Timepoint
Measurement of FBS amount at the beginning of the study (before the start of the intervention) and 3 months after the start of taking lactocare probiotic drug or placebo.
Method of measurement
Fasting blood glucose measured by the glucose oxidase/peroxidase method.

8

Description
Triglyceride (TG)
Timepoint
Measuring the amount of triglycerides at the beginning of the study (before the start of the intervention) and 3 months after the start of taking lactocare probiotic drug or placebo.
Method of measurement
Triglyceride is a form of fat storage in the blood circulation that is measured by an enzyme method.

9

Description
Cholesterol (CHOL)
Timepoint
Cholesterol measurement at the beginning of the study (before the start of the intervention) and 3 months after the start of lactocare probiotic drug or placebo
Method of measurement

Total cholesterol in LDL, VLDL and HDL particles in blood circulation, which is measured by enzyme method.

10

Description
High-density lipoprotein (HDL-c)
Timepoint
HDL measurement at the beginning of the study (before the intervention) and 3 months after the start of lactocare probiotic drug or placebo.
Method of measurement
Cholesterol contained in HDL particles in the circulation, which is measured by an enzymatic method.

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Description
Low-density lipoprotein (LDL-c)
Timepoint
Measuring the amount of LDL at the beginning of the study (before the start of the intervention) and 3 months after the start of taking lactocare probiotic or placebo
Method of measurement
Cholesterol contained in LDL particles in the blood circulation, which is measured by an enzymatic method.

Secondary outcomes

1

Description
Clinical symptoms of patients with type 2 diabetes mellitus in the studied groups
Timepoint
The clinical symptoms of patients with type 2 diabetes will be measured at the beginning of the study (before the intervention) and 90 days after the start of lactocare probiotic medicine.
Method of measurement
The clinical symptoms of type 2 diabetes patients will be measured by examining nutrition (in terms of consumption or non-consumption of probiotic products), culture (having or not having eating and social habits) by an internal medicine specialist or an endocrinologist.

Intervention groups

1

Description
Intervention group: One capsule of lactocare probiotic, daily for 90 days
Category
Treatment - Drugs

2

Description
Control group: one capsule of placebo daily for 90 days
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Diabetes Clinic, Bu Ali Hospital, Zahedan
Full name of responsible person
Mahdi Atabaki
Street address
Bo Ali Hospital, Shohada' Square, Shariati Street, Zahedan
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9815816987
Phone
+98 54 3322 2023
Email
boali@zaums.ac.ir
Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Nur Mohammad Bakhshani
Street address
Daneshgah street
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Phone
+98 54 3337 2116
Fax
+98 54 3337 2116
Email
zaums.research@gmail.com
Web page address
https://zaums.ac.ir/default.page
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zahedan 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
Zahedan University of Medical Sciences
Full name of responsible person
Mahdi Atabaki
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Immunology
Street address
Daneshgah Street
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Phone
+98 54 3337 2151
Email
atabaki80@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Mahdi Atabaki
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Immunology
Street address
Daneshgah street
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Phone
+98 54 3337 2151
Email
atabaki80@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Mahdi Atabaki
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Immunology
Street address
Daneshgah street
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Phone
+98 54 3337 2151
Email
atabaki80@gmail.com
Web page address

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
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Information about the clinical part of the study is made available to patients after identifying individuals, and other information, including molecular, laboratory, and clinical studies, is provided in detail to academic researchers for further research. Be helpful in this regard.
When the data will become available and for how long
The start of the information access period is approximately 4 to 6 months after the publishing the results.
To whom data/document is available
Data from this study are available to participating patients, academic researchers, drug companies, and physicians.
Under which criteria data/document could be used
It is explained to the patients that if the information obtained from this study is aimed at improving the clinical conditions, it should not be suggested to other

patients to takelactocare probiotic medicine because the study is conducted with special criteria and under the supervision of pharmacology and immunology experts and doctors. Internal specialist or endocrinology subspecialist is designed. For academic researchers in order to obtain more information in this field, for example, they can have more maneuver in their future research on the number of samples, the duration of the trial, the dosage of lactocare probiotic drug, and even design stronger studies by using molecular information and methods. do Also, the study information may be useful for the drug manufacturing company to improve the quality of the drug.

From where data/document is obtainable

To obtain patient information, please refer to Dr. Mehdi Atabaki, Ph.D. in Immunology at Bo Ali Zahedan Hospital. Address: Shariati St., Shohada Square, Bu Ali Hospital with zip code: 9816743111 Phone: +98 930 304 3900 Access to other information will be possible by requesting via email to atabaki80@gmail.com.

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

Study information 6 months after the publication of all domestic and foreign articles and receiving complete information from researchers who intend to do research in this field, the information will be provided to them in time frames and according to the preservation of the law of copying and pasting.

Comments