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Efficacy, safety and acceptability of a probiotic with Bacillus coagulans on immunomodulation in healthy volunteers: a randomized, double-blind, placebo-controlled pilot study

Submission date
06/11/2025

Recruitment status
No longer recruiting

Registration date
06/11/2025

Overall study status
Completed

Last Edited
06/11/2025

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
This study looked at whether taking a daily probiotic supplement could help support the immune system and improve overall wellbeing in healthy adults. The probiotic being tested contains Bacillus coagulans, a type of friendly bacteria. Researchers also wanted to check how safe and acceptable the supplement is compared to a placebo (a capsule with no active ingredients).

Who can participate?
The study invited healthy men and women aged 18 to 65 who eat a balanced diet, exercise regularly, and don't have any long-term illnesses or immune-related conditions.

What does the study involve? (for participants)
People who joined the study were randomly given either the probiotic or a placebo capsule to take once a day for 90 days. They visited the clinic twice—once at the start and once at the end of the 90 days. At each visit, a small blood sample was taken to measure immune system markers, and participants filled out a questionnaire about their quality of life. Around halfway through the study, there was a short phone call to check how things were going and ask about any side effects.

What are the possible benefits and risks of participating?
Participants might experience better wellbeing and improved immune function, although this isn't guaranteed. The risks were very low and mostly limited to mild digestive discomfort.

Where is the study run from?
The study was led by two dermatologists, Dr Marina Corral and Dr Nuria Setó Torrent, at Hospital Universitari Sagrat Cor in Barcelona, Spain. It was coordinated by Methodex S.L., also based in Barcelona.

When is the study starting and how long is it expected to run for?
April 2021 to December 2022

Who is funding the study?
The study was sponsored by Nutris Ingredients S.L., a company based in Madrid, Spain.

Who is the main contact?
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Additional identifiers

Protocol serial number
MTH-NUT0121

Study information

Scientific Title
Prospective, double-blind, randomized, single-center pilot clinical study compared with placebo, to assess efficacy, safety and acceptability of a probiotic with Bacillus coagulans on immunomodulation in healthy volunteers

Study objectives
The main objective of this study was to assess the efficacy, safety, and acceptability of an oral probiotic containing Bacillus coagulans on Immunomodulation in healthy adults compared with placebo.

Primary hypothesis: Oral administration of Bacillus coagulans exerts an immunomodulatory effect compared with placebo.

Secondary hypotheses: Oral administration of Bacillus coagulans improves quality of life and it is safe and well-tolerated without adverse effects compared with placebo.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 14/09/2021, CEIm Grupo Hospitalario Quirónsalud-Catalunya (Carrer de Pedro i Pons, 1, Sant Cugat del Vallès, Barcelona, 08195, Spain; +34 935656000; ceic.idcsa.cat@idcsalud.es), ref: 2021/81-DER-HUSC

Primary study design
Interventional

Study design
Randomized placebo-controlled double-blind parallel groups (1:1 allocation)

Study type(s)
Efficacy, Quality of life, Safety

Health condition(s) or problem(s) studied
Immune modulation and quality of life in healthy adults.

Interventions
Participants are randomly assigned (1:1) to receive either the probiotic product or a placebo for 90 days. The experimental group receives one oral capsule daily before meals containing Bacillus coagulans (5×10^9 CFU/day). The control group receives one identical placebo capsule daily with the same appearance and schedule. All participants attend two on-site visits (Day 1 and Day 90) at Hospital Universitari Sagrat Cor for blood sample collection and quality-of-life assessment. A telephone follow-up is performed at mid-study (around Day 45) to monitor adherence and safety.

The randomisation process was computer-generated using R statistical software (RStudio) prior to enrolment. Participants were then assigned in a 1:1 ratio to either the probiotic or placebo group according to this pre-established randomisation list. The allocation was implemented by the CRO (Methodex SL), ensuring double-blind conditions for investigators and participants throughout the study.

Intervention Type
Supplement

Primary outcome(s)
Levels of immunological markers (immunoglobulin A [IgA], immunoglobulin G [IgG], interferon-γ [IFN-γ], and total leukocyte count) measured by blood analysis at baseline (Day 1) and after 90 days of supplementation (Day 90)

Key secondary outcome(s)
1. Health-related quality of life measured using the SF-36 questionnaire at baseline (Day 1) and after 90 days of supplementation (Day 90)
2. Safety and tolerability assessed through participant reports and clinical evaluation at each visit and via follow-up phone call (around Day 45)

Completion date
29/12/2022

Eligibility

Key inclusion criteria
1. Healthy male and female volunteers aged 18–65 years
2. Individuals following a balanced diet according to standard nutritional guidelines
3. Participants performing at least 30 minutes of daily physical activity
4. Good personal hygiene and general health status
5. No psychological or psychiatric disorders
6. No family history of genetically heritable diseases
7. Able to understand the study information and comply with study requirements
8. Willing to provide written informed consent before participation

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
All

Total final enrolment
55

Key exclusion criteria
1. Diagnosis of diabetes mellitus
2. Pregnant or breastfeeding women
3. Presence of autoimmune disease (e.g. Addison's disease, celiac disease, Graves' disease, Hashimoto's thyroiditis, rheumatoid arthritis, multiple sclerosis, systemic lupus erythematosus, type I diabetes, etc.)
4. Current or recent treatment with immunosuppressive drugs
5. Presence of any chronic disease or acute respiratory infection (including common cold, flu, or COVID-19).
6. Use of antibiotics within 10 days prior to study start
7. Intake of probiotics or immune-boosting supplements (e.g. vitamin C, echinacea, royal jelly, multivitamins) within 10 days prior to study start
8. History of drug, alcohol, or substance abuse
9. Participation in another clinical trial within the previous 3 months
10. Any medical or social condition that, in the investigator's opinion, could interfere with study participation or data reliability

Date of first enrolment
17/11/2021

Date of final enrolment
29/03/2022

Locations

Countries of recruitment
Spain

Study participating centre
Hospital Universitari Sagrat Cor – Department of Dermatology
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Sponsor information

Organisation
Nutris We Care About You

Funder(s)

Funder type
Not defined

Funder Name
Nutris We Care About You

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Veronica Gallo (vgallo@nutris.es).

IPD sharing plan summary
Available on request