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Effects of Bacillus coagulans SNZ 1969 on immune health in healthy school-aged children

Submission date
23/10/2025

Recruitment status
Not yet recruiting

Registration date
24/10/2025

Overall study status
Ongoing

Last Edited
24/10/2025

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
Many school-aged children get sick several times a year with upper respiratory infections, such as the common cold, or gastrointestinal infections like the stomach flu. Although children are among the most affected by these infections, there is a noticeable lack of options for natural health supplements that provide strong evidence for reducing the burden of cold and flu-like symptoms for children.
Bacillus coagulans is a type of beneficial bacteria known as a probiotic. It is approved for use in Canada to contribute to healthy gut flora and reduce oral plaque and gingivitis. The purpose of this study is to evaluate how Bacillus coagulans SNZ 1969 (B. coagulans) helps support the immune system in children attending school.

Who can participate?
Healthy males and females between 6 and 12 years of age who are attending school in person during the 2025-2026 cold and flu season to allow for adequate exposure to URTI or GITI pathogens. To avoid confounding effects of pre-existing medical conditions children presenting with a history or presence of a clinically relevant respiratory, pulmonary, or gastrointestinal condition will be excluded at the discretion of the Qualified Investigator. Furthermore, participants consuming immune modulating medications, antibiotics, products containing B. coagulans, or any other probiotic supplement will be excluded unless they have undergone the specified washout. Strict eligibility criteria are designed to reduce confounders on immune health affecting both upper respiratory tract infections and gastrointestinal tract infection symptoms. Children presenting with any other medical condition or lifestyle factor which may affect the safety of their participation or study outcomes will also be excluded.

What does the study involve?
Enrolled participants will be randomly allocated to either probiotic Bacillus coagulans SNZ 1969 or placebo arm. Participants will take either probiotic Bacillus coagulans SNZ 1969 or a placebo every day for 84 days. The study involves assessment of the difference between Bacillus coagulans SNZ 1969 and placebo from baseline to day 28, day 56 and day 84 in incidence, duration, and severity of upper respiratory tract infection (URTI), additional respiratory tract symptoms and gastrointestinal tract infection (GITI) symptoms.
In additional to these, the difference in change between B. coagulans SNZ 1969 and placebo

from baseline (day 0) to day 84 on saliva secretory immunoglobulin A (sIgA) concentrations, serum levels of immunoglobulin A (IgA), G (IgG), E (IgE) and M (IgM); immune response biomarkers and fecal microbiome analysis will be compared.

What are the possible benefits and risks of participating?
The possible benefits may or may not be any immediate benefit to your child, the results of this study will provide some of the required scientific evidence for the study products in this research study. Your collective participation in this study supports the research that is required to ensure the science behind the study products.
All potential risks are disclosed to study participants prior to their participation. Potential side-effects of taking the study product may include:
1. Abdominal discomfort (such as pain, nausea, changes in bowel habits)
2. Dislike of taste
3. Worsening of URTI or GITI symptoms
OTC medications for fever, cough etc. can be taken and use is to be documented as part of concomitant medications. If symptoms persist or worsen, participants will be instructed to contact their healthcare practitioner to ensure that any standard of care treatment can be provided.
Other potential risks associated with this study include venipuncture and the associated risks. Risks associated with venipuncture include pain, bruising, and infection at the site. Alcohol swabs and proper venipuncture procedure will be followed to minimize the risk of infection.

Where is the study run from?
This study will be conducted at the Clinic, KGK Science Inc, London, Ontario, Canada. KGK Science Inc. is a global CRO that has expertise in conducting clinical studies.

When is the study starting and how long is it expected to run for?
September 2025 to May 2026

Who is funding the study?
Sanzyme Biologics Private Limited (India)

Who is the main contact?
Dr David Crowley, dcrowley@kgkscience.com

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Protocol no: 25SACCP01

Study information

Scientific Title
A randomized, double-blind, placebo controlled, parallel clinical trial to investigate the safety and efficacy of Bacillus coagulans SNZ 1969 on immune health in healthy school-aged children

Acronym
BC SNZ 1969

Study objectives
The objective of this study is to investigate the safety and efficacy of Bacillus coagulans SNZ 1969 on the incidence rate, duration, and severity of acute upper respiratory tract infections (URTIs) and gastrointestinal tract infection (GITI) symptoms in healthy school-aged children.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 22/09/2025, UNIVO IRB (4509 Creedmoor Road, Suite 403, Raleigh, 27612, United States of America; +1 (0)919 910 7743; vhaggett@univo-group.com), ref: STU25090169

Study design
Interventional randomized double-blinded (participant, investigator) placebo-controlled parallel-assignment two-arm single-center study

Primary study design
Interventional

Study type(s)
Efficacy, Safety

Health condition(s) or problem(s) studied
Immune health in school-aged children

Interventions

Each participant will be assigned a randomization code according to the order of the randomization list generated. Enrolled participants will be randomized to either of the study arms at Day 0.

Block randomization will be implemented for this study. It is a method that helps to reduce bias and achieve balance in the allocation of participants to study arms. This technique helps to increase the probability that each arm will contain an equal number of individuals by sequencing participant assignments by blocks.

Participants are randomized within blocks so that an equal number are assigned to each study arm. Allocation proceeds by randomly selecting one ordering and assigning the next block of participants to a study group based on a specified sequence. The block size needs to be divisible by the number of study groups.

Active comparator: probiotic Bacillus coagulans SNZ 1969 sachet containing 1 billion CFU/g every day for 84 days
Placebo comparator: Glucidex (maltodextrin), magnesium stearate, banana dry mix flavour, every day for 84 days

Participants will be instructed to fully consume one sachet containing 1 billion CFU/g completely dissolved in approximately 50 ml of water before breakfast starting on Day 1 and throughout the duration of the study.

Intervention Type
Supplement

Primary outcome(s)
1. URTI symptoms. The difference in incidence, duration, and severity (area-under-the-curve [AUC]) of URTI as assessed by the Canadian Acute Respiratory Illness and Flu Scale (CARIFS) from baseline to day 84 between Bacillus coagulans SNZ 1969 and placebo [time frame: baseline to day 84]
2. Additional respiratory tract symptoms. The difference in incidence, duration, and severity (area-under-the-curve [AUC]) of additional respiratory tract symptoms as assessed by Additional Respiratory Tract Symptoms questionnare from baseline to day 84 between Bacillus coagulans SNZ 1969 and placebo [time frame: baseline to day 84]
3. GITI symptoms. The difference in incidence, duration, and severity (AUC) of GITI symptoms as assessed by the GITI Symptoms Questionnaire from baseline to day 84 between Bacillus coagulans SNZ 1969 and placebo [time frame: baseline to day 84]

Key secondary outcome(s))
1. The difference in incidence, duration, and severity (AUC) of URTI as assessed by the CARIFS from baseline to days 28 and 56 between B. coagulans SNZ 1969 and placebo
2. The difference in incidence, duration, and severity (AUC) of additional respiratory tract symptoms as assessed by Additional Respiratory Tract Symptoms questionnare from baseline to days 28 and 56 between B. coagulans SNZ 1969 and placebo
3. The difference in incidence, duration, and severity (AUC) of GITI symptoms as assessed by the GITI Symptoms Questionnaire from baseline to days 28 and 56 between B. coagulans SNZ 1969 and placebo

Additional secondary outcomes:
4. The difference between B. coagulans SNZ 1969 and placebo from baseline to days 28, 56, and

84 on:
4.1. Severity of cold/flu and GITI symptoms as assessed by total and individual daily symptom scores
4.2. Number of missed school days
4.3. Number of well days, related to the absence of cold/flu and GITI symptoms
4.4. Use of prescription and non-prescription cold/flu medications to treat cold or flu symptoms
4.5. Total days of illness
5. Immunoglobulin and immune response biomarkers [time frame: baseline to day 84]
6. The difference in change between B. coagulans SNZ 1969 and placebo from baseline to day 84 on:
6.1. Saliva secretory immunoglobulin A (sIgA) concentrations
6.2. Serum levels of immunoglobulin A (IgA), G (IgG), E (IgE) and M (IgM)
6.3. Immune response biomarkers: CD14, CD163, CD40 (TNFRSF5), CRP (C-Reactive Protein), E-Selectin, Fas (TNFRSF6/Apo1), Fas Ligand (TNFSF6), GCSF, ICAM-1 (CD54), IL-1 alpha (IL-1 F1), IL-1 beta (IL-1 F2), IL-1 R4 (ST2), IL-10, IL-12 p70, IL-13, IL18, IL-2, IL-2 R alpha, IL-4, IL-6, IL-8 (CXCL8), Lipocalin-2 (NGAL), MCP-1 (CCL2), MCP-2 (CCL8), MIF, MIP-1 alpha (CCL3), MIP-1 beta (CCL4), Osteopontin (SPP1), PAI-1, Platelet Factor 4 (CXCL4), Procalcitonin, RAGE, Resistin, Thrombomodulin, TNF alpha, TREM-1, Troponin I, uPAR, VCAM-1 (CD106), VEGF-A.
6.4. Microbiome as assessed by 16s rRNA fecal microbiome analysis

Safety outcomes:
1. Incidence of post-emergent adverse events (AE) [time frame: throughout study duration]
2. Clinically relevant changes in vital signs (blood pressure [BP] and heart rate [HR]) after supplementation [time frame: throughout study duration]

Completion date
31/05/2026

Eligibility

Key inclusion criteria
1. Males and females between 6 and 12 years of age at screening, inclusive
2. Children enrolled in and attending school in person at baseline
3. Willingness to complete questionnaires, records, and diaries associated with the study and to complete all clinic and remote visits
4. A care provider who can reliably bring the participant to study visits. The participant’s primary caregiver must be willing and able to complete the questionnaires
5. The participant or the participant’s parents/guardian are willing and able to provide written assent and/or informed consent as appropriate
6. Agrees to maintain current lifestyle habits (diet, physical activity, medications, supplements, and sleep) as much as possible throughout the study
7. Healthy as determined by medical history as assessed by the Qualified Investigator (QI)

Participant type(s)
Healthy volunteer, Learner/student

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 years

Upper age limit
12 years

Sex
All

Key exclusion criteria
1. Individuals who are pregnant
2. Allergy, sensitivity, intolerance, or dietary restriction preventing consumption of the investigational product or placebo ingredients
3. History or presence of a clinically relevant cardiac, renal, hepatic, endocrine (including diabetes mellitus), respiratory, pulmonary, biliary, metabolic, haematologic, gastrointestinal, or pancreatic disorders, that may affect participation or outcomes as assessed by the QI
4. Confirmed history of COVID-19 infection in the 3 months prior to baseline
5. Immune dysfunction, autoimmune disease, immune compromised and/or taking an immunosuppressive medication, as assessed by the QI
6. Severe environmental allergies requiring medical or need for allergy shots, as assessed by the QI
7. Major surgery in the past 3 months or individuals who have planned surgery during the course of the study. Participants with minor surgery will be considered on a case-by-case basis by the QI
8. Cancer, except skin basal cell carcinoma completely excised with no chemotherapy or radiation with a follow up that is negative. Volunteers with cancer in full remission for more than five years after diagnosis are acceptable
9. Asthma, as assessed by the QI
10. Current use of prescribed and/or over-the-counter (OTC) medications, supplements, and/or consumption of food/drinks that may impact the efficacy and or safety of the investigational product
11. Participation in other clinical research studies 30 days prior to baseline, as assessed by the QI
12. Participant or participant’s caregiver who are cognitively or neurodevelopmentally impaired affecting their ability to give informed consent and/or assent
13. Any other condition or lifestyle factor, that, in the opinion of the QI, may adversely affect the participant's ability to complete the study or its measures or pose significant risk to the participant

Date of first enrolment
15/11/2025

Date of final enrolment
28/02/2026

Locations

Countries of recruitment
Canada

Study participating centre
KGK Science Inc.
275 Dundas Street, Tower A
Suite G02
London
Canada
N6B 3L1

Sponsor information

Organisation
Sanzyme Biologics Private Limited

Funder(s)

Funder type
Industry

Funder Name
Sanzyme Biologics Private Limited

Results and Publications

Individual participant data (IPD) sharing plan
The IPD and datasets generated will be available upon request from KGK Sciences Inc.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			24/10/2025	No	Yes
Participant information sheet	Participant information sheet version 2	11/11/2025	11/11/2025	No	Yes
Protocol file		28/08/2025	24/10/2025	No	No
Statistical Analysis Plan			24/10/2025	No	No