ISRCTN10220812 https://doi.org/10.1186/ISRCTN10220812

Effect of SBO-635 on mouth health

Submission date 05/01/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 01/02/2023	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 01/02/2023	**Condition category** Oral Health	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Bad breath or halitosis can cause social disharmony, embarrassment, frustration, and despair and ultimately affect a person`s personal and professional life. Previous research shows that bacteria in the mouth can positively or negatively influence bad breath. A well-balanced oral bacteria composition is ideal to maintain oral hygiene and prevent bad breath. This study is designed to investigate the effectiveness of the test product in reducing bad breath and oral bacteria composition.

Who can participate?
Healthy adults aged between 21 to 55 years with bad breath/halitosis

What does the study involve?
The study involves using a mouthwash twice daily for 2 weeks and then a break for 2 weeks and then again another mouthwash for 2 more weeks. Mouth bad odour levels and oral bacterial composition will be analysed at starting of the study period, after 2 weeks and at the end of the study period.

What are the possible benefits and risks of participating?
The possible benefit is a reduction in bad breath and the risk is a possible allergic reaction to the study product.

Where is the study run from?
Innovation Labo Research (Japan)

When is the study starting and how long is it expected to run for?
April 2021 to May 2023

Who is funding the study?
Innovation Labo Research (Japan)

Who is the main contact?
Yuki Ikeda, development@innovationlabo.com

Contact information

Type(s)
Scientific

Contact name
Dr Yuki Ikeda

Contact details
Kanaya Bldg 4F
4-11-3
Hatchobori
Chuo-Ku
Japan
104-0032
+81 (0)3 35525335
development@innovationlabo.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IL/SBO 22-0928

Study information

Scientific Title
A crossover, randomized, double-blind, two-arm, placebo-controlled, clinical study to evaluate the efficacy of SBO-635 in halitosis and oral microbiota modulation in healthy adult subjects with halimeter score above 200

Acronym
SBO-HM CT

Study objectives
SBO-635, a fermented polysaccharide-based oral care ingredient that shows microbiota-modulating efficacy, can modulate the oral microbiome to reduce halitosis.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 21/10/2022, Ethics Committee of the Japanese Society of Anti-Aging Nutrition (Fugetsudo building 5FGinza, Chuo-ku, Tokyo 6-6-1104-0061, Japan; +81 (0)3 3552 5277; aki.nomura@jaan.jp), ref: JAAN/HTA 22-1021

Study design
Single-center interventional crossover randomized double-blind two-arm placebo-controlled clinical trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format. Please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Halitosis

Interventions
Trial product: Mouthwash containing SBO-635

Placebo: Sensorially similar mouthwash without SBO-635

Duration: 6 weeks

Administration: Subjects will be asked to do 30 seconds swishing inside the mouth with a mouthwash, twice daily for 2 weeks. Then there is a washout period of 2 weeks during which subjects will not be using the trial or placebo products. After cross-over, there is another 2 weeks of twice-daily mouthwash usage for 2 weeks.

Randomization: Block randomization is used to divide potential patients into m blocks of size 2n, randomize each block such that n patients are allocated to A and n to B then choose the blocks randomly. This method ensures equal treatment allocation within each block if the complete block is used.

Crossover: Subjects in the active group and placebo group will crossover to the placebo group and active group respectively after a washout period of 2 weeks.

All test parameters will be checked at baseline, end of interventional period 1 and end of interventional period 2.

All tests and sample collections will be done between 6 am and 8 am after 8 hours of overnight fasting, without performing any oral hygiene measures in the morning.

Intervention Type
Supplement

Primary outcome measure
Halitosis measured using a Halimeter (Interscan corp., Chatsworth, CA) at baseline (day 0), day 14 and day 42

Secondary outcome measures
Oral microbiome diversity measured using 16S rRNA gene sequencing of the V3/V4 (v3-v7) hypervariable region at baseline, day 14 and day 42

Overall study start date
12/04/2021

Completion date
26/05/2023

Eligibility

Key inclusion criteria
1. Non-smoking healthy subjects between 21 to 55 years (inclusive) of age
2. Subjects with conformed halitosis (Organoleptic score ≥2 and Halimeter score ≥180)
3. Subjects who are free from any active oral infections or inflammatory conditions such as dental caries, mouth ulcers, gingivitis or periodontitis
4. Subjects willing to give written informed consent and willing to comply with the trial protocol
5. Subjects willing to adhere to a standard oral care protocol during the study period
6. Subjects willing to refrain from using alcohol during the study period
7. Subjects who are able to understand the risks/benefits of the protocol
8. Subject should be available for the duration of the study period (6 weeks)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
42

Key exclusion criteria

1. Subjects with a history of oral malignancy
2. Subjects with possible extra oral causes for halitosis: laryngopharyngeal reflux, tonsillitis, sinusitis, metabolic acidosis or alkalosis, renal diseases, liver malfunctions, dental brackets or bridges, dental infections and diabetes mellitus
3. Pregnant or lactating females
4. Subjects who have used oral antibiotics, non-steroid anti-inflammatory drugs (NSAIDs) corticosteroids or nutrition supplements within 3 months from the start of the study
5. Subjects who are participating or have participated in any other clinical trial within 3 months from the start of the study
6. Subjects with a history of psychiatric disorder that may impair the ability of subjects to provide written informed consent
7. Drug or alcohol abusers
8. Any other condition that the Principal Investigator thinks may jeopardize the study outcome

Date of first enrolment
20/02/2023

Date of final enrolment
31/03/2023

Locations

Countries of recruitment
Japan

Study participating centre
Medica Tokyo Laboratories
20-1, 3Chome Nishi-Shinjuku
Shunjuku
Japan
160-0023

Sponsor information

Organisation
Innovation Labo Research

Sponsor details
5F, 1-12-7, Shintomi
Chuo-Ku
Japan
1040032
+81 (0)3 35525335
tokyo@innovationlabo.com

Sponsor type
Industry

Website
https://www.innovationlabo.com/

Funder(s)

Funder type
Industry

Funder Name
Innovation Labo Research

Results and Publications

Publication and dissemination plan
Planned publication a high-impact peer-reviewed journal

Intention to publish date
31/05/2024

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date