ISRCTN74332440 https://doi.org/10.1186/ISRCTN74332440

The improvement effect of probiotics using tablet containing Lactobacillus salivarius WB21 on bad breath

Submission date
27/12/2012

Recruitment status
No longer recruiting

Registration date
10/01/2013

Overall study status
Completed

Last Edited
17/12/2020

Condition category
Signs and Symptoms

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Oral malodor (bad breath) is primarily the result of the breakdown of amino acids in the local debris of the oral cavity by the micro organisms. Because probiotics possess potential capacity for improving microbiota, it may improve oral malodor. Lactobacillus salivarius WB21 has been recognized as a probiotic for oral health, and we previously reported that oral administration of tablets containing L. salivarius WB21 improved oral malodor in a study. The aim in this study was to confirm the effect of probiotics using L. salivarius WB21 on bad breath.

Who can participate?
Eighty-two patients complaining of halitosis (bad breath) were assessed for study eligibility at the Oral Malodor Clinic of Fukuoka Dental College Medical and Dental Hospital, Japan between June 2010 and September 2011. The eligible participants were 26 patients (22 females and four males, age range, 2267 years). They were patients with oral malodor above a questionable level, not currently visiting a dentist for treatment, no acute symptoms requiring immediate oral cavity treatment, no use of probiotic supplements, no antibiotic use within the last month, no daily smoking habit, no systemic illness and no adverse reactions to lactose or fermented milk products.

What does the study involve?
The intervention (treatment) compared test tablets with placebo. All participants received the same treatment that ingested both tablets containing L. salivarius WB21 and placebo. Placebo samples contained only xylitol.

What are the possible benefits and risks of participating?
The participants have a chance of improving oral malodor by oral consumption of test tablets. There is not any side effect.

Where is the study run from?
The study took place at the Oral Malodor Clinic of Fukuoka Dental College Medical and Dental Hospital, Japan.

When is the study starting and how long is it expected to run for?
The participants were recruited between June 2010 and September 2011.

Who is funding the study?
This study was supported in part by a Grant-in-Aid for Young Scientists (no. 23792532), Grant-in-Aid for Scientific Research (no. 23593078) and a Grant-in-Aid for Advanced Science Research from the Ministry of Education, Culture, Sports, Science, and Technology, Japan.

Who is the main contact?
Nao Suzuki
naojsz@college.fdcnet.ac.jp

Contact information

Type(s)
Scientific

Contact name
Dr Nao Suzuki

Contact details
2-15-1, Tamura Sawara-ku
Fukuoka
Japan
814-0193
-
naojsz@college.fdcnet.ac.jp

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A double-blind, randomized, placebo-controlled crossover trial of a Lactobacillus salivarius WB21-containing tablet for treatment of oral malodor

Study objectives
Oral malodor is a common problem in humans. Most oral malodor originates directly from the oral cavity owing to conditions such as periodontitis, tongue debris, poor oral hygiene, deep caries, inadequately fitted restorations, and endodontic lesions. Oral malodor is primarily the result of microbial metabolism of amino acids in local debris in the oral cavity. The most common

compounds associated with oral malodor are volatile sulfur compounds (VSCs), such as hydrogen sulfide (H2S) and methyl mercaptan (CH3SH).

Lactobacillus salivarius WB21 has been recognized as a probiotic for oral health, and we previously reported that oral administration of tablets containing L. salivarius WB21 improved oral malodor in an open trial. In this study, we conducted a 14-day, double-blind, placebo-controlled, randomized crossover trial of tablets containing L. salivarius WB21 or placebo taken orally by patients having oral malodor to confirm the authenticity of the effect of this organism on oral malodor.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee for Clinical Research of Fukuoka Dental College and Fukuoka College of Health Sciences, July 2, 2008, approval number 125

Study design
Randomized double-blind crossover placebo-controlled clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Oral malodor

Interventions
The tablets (MINNA NO ZENDAMAKIN WB21 TABLET®; Wakamoto Pharmaceutical Co., Tokyo, Japan) contained 6.7 × 108 colony-forming units (CFU) of L. salivarius WB21 and 280-mg xylitol per tablet.

Placebo samples contained only xylitol (280 mg/tablet).

The dose throughout the test period was maintained at three tablets per day, taken orally after eating. Subjects were directed to place a tablet on the tongue for a few minutes and allow it dissolve.

The period that the patients had tablets was four weeks, 2 weeks for test tablets and 2 weeks for placebo tablets with a wash out period of 2 weeks.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Lactobacillus salivarius WB21

Primary outcome measure
1. Organoleptic (OLT) score: The OLT scores were estimated by two of the three evaluators (with training and experience in calibration tests) using a scale of 0 to 5 (0, absence of oral malodor; 1, questionable odor; 2, slight malodor; 3, moderate malodor; 4, strong malodor; 5, severe malodor), and the mean of the scores given by the evaluators was used.
2. Total volatile sulfur compounds concentration: The total VSCs condition was measured by gas chromatography
3. Periodontal health: Periodontal health was assessed using the average probing pocket depth (PPD) and the number of bleeding on probing (BOP) sites. PPD and BOP were measured at six points around each tooth in all subjects.
4. Plaque control was evaluated using the Silness Löe Plaque Index
5. Degree of tongue coating was determined by tongue coating score (TCS): 0, no tongue coating; 1, thin tongue coating covering less than one-third of the tongue dorsum; 2, thick tongue coating covering approximately one-third of the tongue dorsum or thin tongue coating covering one-third to two-thirds of the tongue dorsum; 3, thick tongue coating covering one-third to two-thirds of the tongue dorsum or thin tongue coating covering more than two-thirds of the tongue dorsum; and 4, thick tongue coating more than two-thirds of the tongue dorsum.
6. Volume of stimulated salivary flow was measured using the chewing gum test. The patient was asked to pool saliva in the oral cavity and spit into a vessel each minute throughout a 5-min collection period.

Secondary outcome measures
1. Volatile sulfur compound concentration
2. The number of each probing depth
3. The number of oral bacteria in the saliva

Overall study start date
01/06/2010

Completion date
30/09/2011

Eligibility

Key inclusion criteria
1. 26 eligible patients (22 females and four males; mean age, 43.5 ± 11.5 years; age range, 2267 years)

2. Oral malodor above a questionable level (OLT score ≥ 1.5)
3. Not currently visiting a dentist for treatment
4. No acute symptoms requiring immediate oral cavity treatment
5. No use of probiotic supplements
6. No antibiotic use within the last month
7. No daily smoking habit
8. No systemic illness
9. No adverse reactions to lactose or fermented milk products

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
26 eligible patients (22 females and four males; mean age, 43.5 ± 11.5 years; age range, 2267 years)

Key exclusion criteria
Does not meet inclusion criteria

56 were excluded: 48 did not meet the inclusion criteria, three refused to participate, and five had personality traits that were considered difficult for adherence to the protocol.

Date of first enrolment
01/06/2010

Date of final enrolment
30/09/2011

Locations

Countries of recruitment
Japan

Study participating centre
2-15-1, Tamura Sawara-ku
Fukuoka
Japan
814-0193

Sponsor information

Organisation
Fukuoka Dental College (Japan)

Sponsor details
c/o Nao Suzuki, DDS, PhD
Section of General Dentistry
Department of General Dentistry
Fukuoka
Japan
814-0193
+81 92 801 0411
naojsz@college.fdcnet.ac.jp

Sponsor type
University/education

Website
http://www.fdcnet.ac.jp

ROR
https://ror.org/04zkc6t29

Funder(s)

Funder type
Government

Funder Name
Ministry of Education, Culture, Sports, Science, and Technology (Japan) - Grant-in-Aid for Young Scientists (no. 23792532), Grant-in-Aid for Scientific Research (no. 23593078) and a Grant-in-Aid for Advanced Science

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2014	17/12/2020	Yes	No