

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

<b>Submission date</b> 27/12/2012	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 10/01/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 17/12/2020	<b>Condition category</b> Signs and Symptoms	<input type="checkbox"/> 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, 22-67 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?

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## Contact information

### Type(s)

Scientific

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## 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 (H<sub>2</sub>S) and methyl mercaptan (CH<sub>3</sub>SH).

*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  $6.7 \times 10^8$  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 Loe 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,  $43.5 \pm 11.5$  years; age range, 22-67 years)

2. Oral malodor above a questionable level (OLT score  $\geq 1.5$ )
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,  $43.5 \pm 11.5$  years; age range, 22-67 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**

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**Sponsor information**

**Organisation**

Fukuoka Dental College (Japan)

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**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?
<a href="#">Results article</a>	results	01/04/2014	17/12/2020	Yes	No