

# Effect of oral probiotics on skin wrinkle and hydration in adult women

<b>Submission date</b> 22/10/2020	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 22/10/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 17/08/2022	<b>Condition category</b> Skin and Connective Tissue Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Bifidobacteria are bacteria that live in the human gut. They help to improve the digestion of food and suppress the growth of harmful bacteria. Gut bacteria may also have other positive effects on human health. Bifidobacteria and components derived from Bifidobacteria have been studied for their properties in enhancing skin hydration and structure. The aim of this study is to examine the effects of taking Bifidobacterium by mouth on the skin, including wrinkles, dryness and elasticity.

### Who can participate?

Korean women aged 30-60

### What does the study involve?

Participants will be randomly allocated to one of two groups. Both groups will take a capsule by mouth once a day for 12 weeks. For one group, the capsule will contain Bifidobacterium. For the other, the capsule will be a dummy capsule containing no active ingredient (placebo). The capsules will look the same and neither the participants nor the researchers will know which capsule a participant is taking. 1. Skin wrinkles and hydration are measured at the start of the study and after 4, 8 and 12 weeks

### What are the possible benefits and risks of participating?

Participants may not benefit from the study as it is not known whether the test product will improve skin wrinkles or hydration. However, the study will extend the understanding of the effects of oral Bifidobacterium on skin wrinkles and hydration. As for potential risks and disadvantages, blood sampling may cause a hematoma (bruise) or fainting, and the skin measurements and restrictions related to the measurements may cause inconvenience. The test product is not known to cause side effects. There is a small risk of possible allergy or intolerance, as for any dietary product.

### Where is the study run from?

Danisco Sweeteners Oy (Finland)

When is the study starting and how long is it expected to run for?  
September 2019 to April 2021

Who is funding the study?  
Danisco Sweeteners Oy (Finland)

Who is the main contact?  
Dr Ja Hyun Ryu  
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## Additional identifiers

**EudraCT/CTIS number**  
Nil known

**IRAS number**

**ClinicalTrials.gov number**  
Nil known

## Secondary identifying numbers

NH-10011

# Study information

## Scientific Title

Effects of Bifidobacterium on skin wrinkle, hydration, transepidermal water loss, elasticity and gloss: a randomized, double-blind, placebo-controlled, and parallel clinical trial

## Acronym

RV\_StructProb-B

## Study objectives

Consumption of probiotics reduces skin wrinkles and enhances skin hydration in adult women.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved 06/08/2020, DERMAPRO Ltd. Institutional Review Board (IRB) (DERMAPRO Ltd. Institutional Review Board, 4F, Bangbaejoongang-ro 30, Seocho-gu, Seoul, Korea, +82 (0)2 597 5435; dermapro@dermapro.co.kr), ref: 1-220777-A-N-01-DICN20182

## Study design

Randomized double-blind parallel placebo-controlled 12-week intervention study

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Other

## Study type(s)

Treatment

## Participant information sheet

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

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

Skin wrinkles and dry skin

## Interventions

Participants are randomly allocated to one of two treatment groups in equal proportions applying block randomization. Participants take one daily capsule of the test product (Bifidobacterium in microcrystalline cellulose) or placebo (microcrystalline cellulose) for 12 weeks with follow-up visits at 4, 8 and 12 weeks.

## **Intervention Type**

Supplement

### **Primary outcome measure**

1. Skin wrinkles measured with PRIMOS® premium from Crow's feet at 4, 8 and 12 weeks
2. Skin hydration measured from cheek, forearm and back of hand with corneometer and moisturemeter at baseline, 4, 8 and 12 weeks

### **Secondary outcome measures**

1. Transepidermal water loss measured with evaporimeter from cheek, forearm and back of hand at baseline, 4, 8 and 12 weeks
2. Skin elasticity measured with cutometer from cheek at baseline, 4, 8 and 12 weeks
3. Skin gloss measured with SkinGlossMeter from cheek at baseline, 4, 8 and 12 weeks
4. Body composition measured with Inbody 330 analyzer at baseline and 2 weeks
5. Facial image measured using VISIA-CR® skin analysis system at baseline and 4, 8 and 12 weeks
6. Product efficacy assessed using an efficacy questionnaire at 4, 8 and 12 weeks
7. Product usability assessed using a usability questionnaire at 12 weeks

### **Overall study start date**

19/09/2019

### **Completion date**

30/04/2021

## **Eligibility**

### **Key inclusion criteria**

1. Korean female subjects aged between 30 and 60
2. Dry skin on their cheek (hydration value is below 48 A.U. by Corneometer®)
3. Skin wrinkles over grade 3 by DERMAPRO standard photograph
4. No chronic or acute disease including skin disease
5. Signed informed consent
6. Cooperative and available for follow-up during the study period

### **Participant type(s)**

Healthy volunteer

### **Age group**

Other

### **Sex**

Female

### **Target number of participants**

170

### **Key exclusion criteria**

1. Consumed probiotics as dietary supplements, food or beverage products during the last 2 weeks
2. Pregnant, nursing or planning to become pregnant

3. Irritation or symptomatic allergy for food including ingredients of cosmetic, medical and test product.
4. Took oral or topical antibiotics during the previous 3 months
5. Took oral retinoid/steroid drug or topical application included steroid during previous 6 months
6. Use functional cosmetics for improvement of skin wrinkle, hydration and elasticity within 3 months
7. Have an experience on the test site (skin decortications, botox and other skin treatment)
8. Participated in a previous study without an appropriate intervening period (3 months) between studies
9. Have a disease which affects the study (e.g. cardiovascular, kidney, liver, thyroid, gastrointestinal disease, gout)
10. Any skin disease (e.g. atopic dermatitis) at the test site
11. Any chronic disease (e.g. diabetes, asthma, high blood pressure) or psychiatric disorder (e.g. depression, schizophrenia, alcoholism, drug addiction)
12. Take a medicine for the treatment of obesity (e.g. antidepressants, anorectics), contraceptives, hormones or diuretics
13. Drink excessive alcohol (over 30 g alcohol per day)
14. Sensitive or hypersensitive skin
15. Damaged skin in or around the test area which includes sunburn, tattoos, scars or other disfiguration on the test area
16. Abnormal result in screening clinical chemical analysis by medical specialist
17. Problem which may interfere with the aim of the study as judged by the principal investigator

**Date of first enrolment**

26/10/2020

**Date of final enrolment**

05/02/2021

## Locations

**Countries of recruitment**

Korea, South

**Study participating centre**

**DERMAPRO Ltd.**

4F, Bangbaejoongang-ro 30, Seocho-gu

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## Sponsor information

**Organisation**

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### Sponsor type

Industry

## Funder(s)

### Funder type

Industry

### Funder Name

Danisco Sweeteners Oy

## Results and Publications

### Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal. No additional documents have been published or are planned to be published at the moment.

### Intention to publish date

31/12/2022

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to the investigational product being a food supplement, thus there is no regulatory obligation to supply participant-level data.

### IPD sharing plan summary

Not expected to be made available

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		18/05/2022	17/08/2022	Yes	No