

# Effect of oral probiotics on skin hydration in adults during 12 weeks

<b>Submission date</b> 06/10/2020	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 07/10/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 12/08/2024	<b>Condition category</b> Skin and Connective Tissue Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## 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 hydration and moisture evaporation.

### Who can participate?

Adults aged 20-65 years old with dry skin

### 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.

### 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 hydration. However, the study will extend the understanding of the effects of oral Bifidobacterium on skin hydration and skin wellbeing. As to potential risks and disadvantages due to study procedures, blood sampling may cause a hematoma or fainting, and the skin measurements and restrictions related to the measurements may cause inconvenience. The test product is not known to cause adverse effects, except a 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 May 2021

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

Who is the main contact?  
Mark Haupt, MD  
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## Contact information

### Type(s)

Public

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## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

NH-10012

# Study information

## Scientific Title

Effect of oral probiotic supplement improving skin hydration on adults during 12 weeks of intervention: a triple-blind, randomized, placebo-controlled trial

## Acronym

RL\_AquaProb

## Study objectives

Consumption of probiotic enhances stratum corneum hydration in healthy adults with dry skin.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved 25/09/2020, Ethics Committee, Hospital District of Southwest Finland (Tyks U-hospital, Kiinamyllynkatu 4-8, UB3, PO Box 52, Turku, FI-20521, Finland; +358 (0)2 313 5010, +358 (0)2 313 0047; eettinen.toimikunta(at)tyks.fi, firstname.lastname(at)tyks.fi), ref: ETMK 55 /1801/2020

## Study design

Randomized triple-blind parallel placebo-controlled interventional 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 contact details to request a participant information sheet

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

Dry skin

## Interventions

Participants are randomly allocated to one of two treatment groups in equal proportions applying block randomization. Randomization is stratified by gender.

Participants take one daily capsule of verum (Bifidobacterium in microcrystalline cellulose) or placebo (microcrystalline cellulose) for 12 weeks with follow-up visits at 4, 8 and 12 weeks.

During the study participants will need to follow some lifestyle restrictions to allow reliable measurements of the selected skin properties. These restrictions include consumption of probiotics, use of certain topical products and harsh skin care practices (i.e. peeling of skin on areas to be measured). Also, before the visits washing of skin areas to be measured is prohibited. The study includes five visits to the study clinic. All visits will be carried out at CRST's clinics in Turku or Helsinki, Finland.

**Intervention Type**

Supplement

**Primary outcome measure**

Stratum corneum hydration measured with corneometer from cheek, neck and forearm from baseline to 12 weeks

**Secondary outcome measures**

Transepidermal water loss measured with evaporimeter from cheek, neck and forearm from baseline to 12 weeks

**Overall study start date**

19/09/2019

**Completion date**

25/05/2021

**Eligibility****Key inclusion criteria**

1. Consent to participate in the study and willing to comply with the protocol and study restrictions
2. Females and males aged 20-65 years at randomization
3. Corneometer confirmed dry skin, arbitrary unit value under 45, measured from cheek, neck and anterior forearm. A series of 6 measurements will be taken and the middle 4 values will be used to calculate the mean value, which will be expressed in arbitrary units (a.u.). All 6 values from each location will be recorded.
4. Dry skin by self-assessment
5. Females of childbearing potential to follow a medically approved contraceptive method

**Participant type(s)**

Healthy volunteer

**Age group**

Other

**Sex**

Both

**Target number of participants**

100 (50 in test group and 50 in placebo group)

**Total final enrolment**

**Key exclusion criteria**

1. Participation in any other clinical trial within the past 2 months before the randomization or planning to do so during the study
2. Unable or unwilling to comply with study procedures
3. Allergy or intolerance to any ingredient in the investigational products
4. Currently diagnosed with atopic dermatitis (AD)
5. Current or planned use of corticosteroids, retinoids or UV-treatment
6. Use of systemic steroids or systemic antibiotics in the 6 months before randomization
7. Use of topical corticosteroids or antibiotics prescribed by a physician or as OTC products in the 2 months before randomization
8. Wounds, scars (including severe acne scars and large burn scars) or tattoos at the skin sites to be examined in this study
9. History of any cosmetic medical treatment (such as medical chemical- or laser peelings or injections of Botox). Non-cosmetic treatment is not an exclusion criterion unless at site of measurement.
10. History of any cosmetic/beauty treatments (such as photofacial or injections of hyaluronic acid, or collagen) at the sites to be examined in this study in the past one year or intention to receive such during the study
11. Exposure to UV light treatment (such as solarium) or extensive sun bathing (i.e. skin has reacted to sun bathing) in the past two months before randomization or intention of such during the study
12. Screening hematology, serum and urinary laboratory analyses results that are deemed clinically significantly abnormal by the investigator
13. Pregnant or breastfeeding or planning pregnancy during the study
14. Otherwise considered unsuitable for the study by the principal investigator

**Date of first enrolment**

15/10/2020

**Date of final enrolment**

23/02/2021

**Locations****Countries of recruitment**

Finland

**Study participating centre****CRST Oy**

Itäinen Pitkätatu 4 B, 3rd floor/3.krs

Turku

Finland

FI-20520

**Study participating centre**

**CRST Oy**  
Energiakatu 4  
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## **Sponsor information**

**Organisation**  
Danisco Sweeteners Oy

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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. The full study protocol and statistical analysis plan won't be available, but the study methods and statistical analyses will be reported in the publication in detail.

**Intention to publish date**  
31/12/2024

**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 no regulatory obligation requests to supply participant-level data.

**IPD sharing plan summary**

Not expected to be made available