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Effect of oral probiotics on skin wrinkles and hydration in adult women

Submission date	Recruitment status	[X] Prospectively registered
28/09/2020	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
05/10/2020	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
09/01/2025	Skin and Connective Tissue Diseases	

Plain English summary of protocol

Background and study aims
Bifidobacteria are bacteria that live in the human gut. They help to improve digestion of food and suppress the growth of harmful bacteria. Gut bacteria may also have other positive effects on human heath. 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 years

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 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 March 2021

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

Who is the main contact?
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Contact information

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Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
NH-10010

Study information

Scientific Title
Effects of Bifidobacterium on skin wrinkle, hydration, ransepidermal water loss (TEWL), elasticity and gloss: a randomized, double-blind, placebo controlled, parallel clinical trial

Acronym
RM_StructProb-A

Study objectives
Consumption of a Bifidobacterium-based probiotic 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 (4F, 30, BangbaeJungang-ro, Seocho-gu, Seoul, Korea; +82-2-597-5435; dermapro@dermapro.co.kr), ref: 1-220777-A-N-01-DICN20181

Study design
Randomized double-blind parallel placebo-controlled study

Primary study design
Interventional

Study type(s)
Treatment

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.

They receive 1 daily capsule of test product (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 exposure to excessive sunlight. The study includes 5 visits to the study clinic. All visits will be carried out at DERMAPRO Ltd., Seoul, Korea. Before each visit, make-up needs to be avoided to assure reliable measurement results.

Intervention Type
Supplement

Primary outcome(s)

1. Skin wrinkles around crow’s feet measured with PRIMOS® imaging technology at baseline and 4, 8 and 12 weeks.
2. Skin hydration measured at cheek, forearm and back of hand with corneometer and moisturemeter at baseline and 4, 8 and 12 weeks.

Key secondary outcome(s))
1. Transepidermal water loss from cheek, forearm and back of hand measured using evaporimeter at baseline and 4, 8 and 12 weeks
2. Cheek skin elasticity measured using cutometer at baseline and 4, 8 and 12 weeks
3. Cheek skin gloss measured using SkinGlossMeter at baseline and 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. Participant's impression of product efficacy assessed using an efficacy questionnaire at 4, 8 and 12 weeks
7. Participant's impression of product usability assessed using a usability questionnaire at at 12 weeks

Completion date
15/03/2021

Eligibility

Key inclusion criteria
1. Korean female subjects aged between 30 and 60 years.
2. Dry skin on cheek (hydration value is below 48 arbirary units [AU] by Corneometer®)
3. Skin wrinkles of over grade 3 by DERMAPRO standard photograph
4. No chronic or acute disease, including skin disease
5. Signed informed consent for the study.
6. Cooperative and available for follow-up during the study period

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
30 years

Upper age limit
60 years

Sex
Female

Total final enrolment
160

Key exclusion criteria
1. Has 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 to food, including ingredients of cosmetic, medical and test products
4. Has taken oral or topical antibiotics during the previous 3 months
5. Has taken oral retinoid/steroid drugs or topical applications including steroids during previous 6 months
6. Has used functional cosmetics for improvement of skin wrinkle, hydration and elasticity within the last 3 months
7. Previous interventions at test site (e.g. skin decortications, Botox and other skin treatments)
8. Has participated in a previous study without an appropriate intervening period (3 months) between studies
9. Has disease which might affect the study (e.g. cardiovascular, kidney, liver, thyroid, gastrointestinal disease, gout)
10. Any skin disease (e.g. atopic dermatitis) at 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 treatment of obesity (e.g. antidepressants, anorectics), contraceptives, hormones or diuretics
13. Take 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. Has an abnormal result in screening clinical chemical analysis by medical specialist
17. Has any problem which may interfere with the aim of the study as the judgment of the principal investigator

Date of first enrolment
06/10/2020

Date of final enrolment
18/12/2020

Locations

Countries of recruitment
Korea, South

Study participating centre
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Sponsor information

Organisation
Danisco Sweeteners Oy

Funder(s)

Funder type
Industry

Funder Name
Danisco Sweeteners Oy

Results and Publications

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?
Basic results		05/12/2024	09/01/2025	No	No