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

Submission date
22/10/2020

Recruitment status
No longer recruiting

Registration date
22/10/2020

Overall study status
Completed

Last Edited
17/08/2022

Condition category
Skin and Connective Tissue Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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?
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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.
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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?
Results article		18/05/2022	17/08/2022	Yes	No