ISRCTN10965433 https://doi.org/10.1186/ISRCTN10965433

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

Submission date
06/10/2020

Recruitment status
No longer recruiting

Registration date
07/10/2020

Overall study status
Completed

Last Edited
12/08/2024

Condition category
Skin and Connective Tissue Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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?
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Contact information

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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. pealing 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 check, neck and forearm from baseline to 12 weeks

Secondary outcome measures
Transepidermal water loss measured with evaporimeter from check, 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 Pitkäkatu 4 B, 3rd floor/3.krs
Turku
Finland
FI-20520

Study participating centre

CRST Oy
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Sponsor information

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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