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Effects of cosmetics on the skin microbiome of faces with different hydration levels

Submission date
07/08/2017

Recruitment status
No longer recruiting

Registration date
09/08/2017

Overall study status
Completed

Last Edited
02/04/2019

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Background and study aims
Skin hydration is one of the most important factors affecting the properties and functions of the skin, and an adequate level of skin hydration is critical for maintaining healthy skin. The aim of this study is to find out whether using basic cosmetics on dry skin might restore skin hydration and change the bacteria present on the skin.

Who can participate?
Healthy Korean female volunteers, aged 26–53

What does the study involve?
Participants are divided into two groups according to the hydration levels of their cheek skin: either the high hydration group or the low hydration group. Participants also apply a set of basic cosmetics twice a day (morning and evening) onto their faces for 4 weeks after facial washing with a cleanser. The types of bacteria living on the skin, skin hydration, water loss, and roughness are compared between the two groups.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Chung-Ang University (South Korea)

When is the study starting and how long is it expected to run for?
June 2015 to July 2015

Who is funding the study?
Coway Cosmetics R&D Center (South Korea)

Who is the main contact?
Dr Hyo Jung Lee

Contact information

Type(s)
Scientific

Contact name
Dr Hyo Jung Lee

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1-220777-A-N-02-DICN15101

Study information

Scientific Title
Effects of cosmetics on facial skin microbiome

Study objectives
The use of basic cosmetics on dry skin might restore skin biophysical parameters, including hydration level, as well as change microbial communities in dry skin to resemble those in normal skin.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Dermapro Ltd. Institutional Review Board, 19/06/2015, ref: 1-220777-A-N-02-DICN15101

Study design
Non-randomised study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Home

Study type(s)
Quality of life

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

Health condition(s) or problem(s) studied
Facial skin microbiome

Interventions
Participants were divided into two groups, high hydration group (HHG; n = 16, ≥ 50 A.U., arbitrary units) and low hydration group (LHG; n = 14, < 50 A.U.), according to the hydration levels in their facial cheek skin. Bacterial communities of facial skin were compared between the two groups, together with measurements of skin biophysical parameters (skin hydration, transepidermal water loss [TEWL], and roughness).

In addition, the effects of basic cosmetics on skin biophysical parameters and the facial skin microbiome were investigated in the two groups. A set of basic cosmetics, consisting of skin softener (solubilized type), lotion (oil-in-water (O/W) emulsion type), essence (solubilized type), and cream (O/W emulsion type) containing moisturizing compounds was prepared and sequentially applied twice a day (morning and evening) for four weeks on their faces after facial washing with a cleanser.

Intervention Type
Other

Primary outcome measure
Measurements of skin biophysical parameters and swab sampling of facial cheek skin performed just before the use of the cosmetics and at two and four weeks after use of the cosmetics:
1. Skin hydration values measured using a Corneometer CM825 instrument (Courage + Khazaka Electronic Gmbh, Germany)
2. Skin transepidermal water loss (TEWL) measured with open-chamber Tewameter TM300 (Courage + Khazaka Electronic Gmbh, Germany), according to the manufacturer’s instructions
3. Facial skin roughness analyzed using the three-dimensional (3D) skin imaging system PRIMOS® premium (GFMesstechnik GmbH, Germany)
4. Bacterial communities analyzed using pyrosequencing using a 454 GS FLX Titanium Sequencing System (Roche, Germany) at Chunlab (Korea)

Secondary outcome measures
No secondary outcome measures

Overall study start date
02/06/2015

Completion date
31/07/2015

Eligibility

Key inclusion criteria
Healthy Korean female volunteers (age from 26–53 years)

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Female

Target number of participants
30

Key exclusion criteria
1. Pregnant or lactating
2. Performed a similar study within three months
3. Sensitive and hypersensitive skin
4. Moles, acne, telangiectasia, etc at the skin under study
5. Used similar cosmetics or took antibiotics within three months
6. Chronic diseases (asthma, diabetes mellitus, hypertension, etc)
7. Atopic dermatitis

Date of first enrolment
02/06/2015

Date of final enrolment
15/06/2015

Locations

Countries of recruitment
Korea, South

Study participating centre
Chung-Ang University
Seoul
Korea, South
06974

Sponsor information

Organisation
Coway

Sponsor details
Coway Cosmetics R&D Center
Seoul
Korea, South
08502

Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Coway Cosmetics R&D Center

Results and Publications

Publication and dissemination plan
This study will be published in a peer-reviewed journal in 2017.

Intention to publish date
31/12/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Hyo Jung Lee.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file		08/08/2017	02/04/2019	No	No