ISRCTN10770381 https://doi.org/10.1186/ISRCTN10770381

Is a mixture of selected probiotic strains effective in improving eczema related symptoms?

Submission date
02/03/2020

Recruitment status
No longer recruiting

Registration date
05/03/2020

Overall study status
Completed

Last Edited
13/08/2021

Condition category
Skin and Connective Tissue Diseases

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

Plain English summary of protocol

Background and study aims
Atopic Dermatitis (AD) is an inflammatory, chronic, pruritic skin disease with a large scale of severity, and a high rate of recurrence and infections due to scarring, which can really affect health-related quality of life. AD related symptoms are itching, redness, dry & scaly skin and recurrent eczematous lesions. Almost 60% of the world population, especially children, suffers from AD.
AD development is characterized by external stimuli (allergens), immune mechanisms (inflammatory cytokines) and alteration of gut and skin microbial community. The correlation between skin and intestine, the so-called gut–skin axis, relies on the concept that gut unbalances can affect skin by inducing systemic inflammation and by triggering dermatological diseases like AD. Conversely, the gut microbiome can strongly influence the host immune system providing protection against pathogens and triggering an immune protective response. So, modulation of gut microbiome in order to achieve a positive effect on the skin provides a safe and innovative approach to skin diseases. Probiotics administration represents a well-recognized approach to modulate gut microbiome, and as referring to AD, several studies pointed at such treatment to ameliorate AD conditions and to prevent recurrences.
The aim of the clinical study is to evaluate the efficacy of a treatment with a food supplement containing a mixture of probiotics (Lactobacillus plantarum, Lactobacillus reuteri and Lactobacillus rhamnosus), specifically selected in terms of post-biotic metabolites and B-group vitamins production, anti-inflammatory and anti-oxidant capacity and anti-microbial activity against skin pathogens, in ameliorating AD symptoms and improving the skin conditions, furthermore the effect of such probiotic mixture on the expression inflammatory markers in skin tape stripping was investigated.

Who can participate?
Healthy adult volunteers, 20 to 50 years old, with a mild-moderate score of Atopic Dermatitis by SCORAD

What does the study involve?
Participants will be randomly allocated to take one capsule a day of the food supplement or the

placebo with a glass of water, away from meals, for 56 days. AD symptoms and skin parameters will be analyzed at the enrollment (T0d), during products intake (T28d and T56d), and after a follow-up of 28 days without taking products (T84d); anti-inflammatory parameters will be measured on skin tape stripping sampled at T0d T28d, and T56d.

What are the possible benefits and risks of participating?
Benefits associated with products use are amelioration of AD symptoms and skin conditions. Risks associated with the intake of the products are considered from low to very low, in absence of allergy/intolerances to product ingredients; other ingredients in the formula of the product are commonly used in dietary supplements. All the instrumental measurements carried out are not invasive and no skin side effects are expected from the measurement process.

Where is the study run from?
Complife Italia Srl (Italy)

When is the study starting and how long is it expected to run for?
October 2018 to April 2019

Who is funding the study
Regione Lombardia (Italy)

Who is the main contact
Dr. Francesco Tursi
francesco.tursi@complifegroup.com

Contact information

Type(s)
Scientific

Contact name
Dr Francesco Tursi

ORCID ID
https://orcid.org/0000-0002-0055-5925

Contact details
COMPLIFE ITALIA Srl
Via Guido Rossa 1
Garbagnate Milanese
Italy
20024
+39 (0)2 99025138
francesco.tursi@complifegroup.com

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
E.HU.027-0080.05.004L_2018/2278

Study information

Scientific Title
Efficacy of a probiotic supplement in improving atopic dermatitis symptoms. A randomized double blind placebo controlled clinical trial

Study objectives
The administration of a food supplement containing selected probiotic strains ameliorates atopic dermatitis symptoms

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 04/09/2018, Independent Ethical Committee for Non-Pharmacological Clinical Study Trials (Via XX Settembre 30/4, 16121Genova, Italy; +39(0)10 5454842; a. scudieri@studinonfarmacologici.it), ref: 2018/09

Study design
Single-centre randomized double-blind placebo-controlled parallel-group

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Atopic dermatitis

Interventions
Subjects aged between 18 and 50 years showing a mild-moderate score of atopic dermatitis (AD) diagnosed by SCORAD, will be equally randomized in two groups to receive one capsule/day of food supplement or placebo for a period of 56 days and will be followed up for a further period of 28 days from the last ingestion of the capsules.

A restricted randomization list was generated by the in-site Study Director using an appropriate statistic algorithm (“Wey’s urn”). Randomization list and envelope containing information on the products were stored by the in-site Study Director, under appropriate safety conditions in a place that is not accessible neither to volunteers nor to the experimenter.

Intervention Type
Supplement

Primary outcome(s)
1. Clinical assessment of the SCORAD Index evaluated by a dermatologist at the beginning of the study (T0d), throughout the intake of the products (T28d and T56d) and 4 weeks after the

intake of the products (T84d)
2. Clinical assessment of Skin smoothness evaluated by a dermatologist at the beginning of the study (T0d), throughout the intake of the products (T28d and T56d) and 4 weeks after the intake of the products (T84d)
3. Determination of the Skin moisturization evaluated as Skin Moisturization Index (Corneometer method) and Trans Epidermal Water Loss (TEWL) at the beginning of the study (T0d), throughout the intake of the products (T28d and T56d) and 4 weeks after the intake of the products (T84d)
4. Cytokine expression such as TNFα (general), TARC (Thymus and activated-regulated chemokine) and TSLP (Thymic Stromal Lymphopoietin) measured by ELISA on skin tape stripping sampled at the beginning of the study (T0d) and throughout the intake of the products (T28d and T56d)

Key secondary outcome(s))
1. Relief from skin discomfort evaluated using a self-assessment questionnaire administered at the end of treatment (T56d) and after the follow-up period (T84d)
2. Quality of life evaluated using a self-assessment questionnaire administered at the end of treatment (T56d) and after the follow-up period (T84d)

Completion date
19/04/2019

Eligibility

Key inclusion criteria
1. Aged 18-50 years, with Phototype I to IV
2. Mild to moderate SCORAD (between 15 and 25)
3. Willingness to use during all the study period only the products to be tested
4. Subjects who have not been recently involved in any other similar study
5. Willingness to not use products likely to interfere with the products to be tested
6. Willingness to not vary the normal daily routine (i.e. lifestyle, physical activity, etc.)

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
50 years

Sex
All

Total final enrolment
80

Key exclusion criteria
1. Current antibiotic administration
2. Known history of chronic medical condition such as congenital heart disease, liver or kidney disease, or immune deficiency
3. Treatment with probiotics in the 6 months preceding enrollment
4. Treatment with steroids and antihistamines systemically in the three months prior to enrollment
5. Topical treatments with immunomodulators (tacrolimus or pimecrolimus) in the three months prior to enrollment
6. Acute or chronic infectious diseases
7. Subjects who has used sun-beds or self-tanning product for one month before the study or intend to use it during the present study

Date of first enrolment
08/10/2018

Date of final enrolment
23/11/2018

Locations

Countries of recruitment
Italy

Study participating centre
Complife Italia Srl
Via Mons. Angelini 21
San Martino Siccomario (PV)
Italy
27028

Sponsor information

Organisation
Complife Italia Srl

Funder(s)

Funder type
Government

Funder Name
Regione Lombardia

Alternative Name(s)
Lombardy Region, Region of Lombardy

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Italy

Results and Publications

Individual participant data (IPD) sharing plan
Raw data will be stored in Complife servers. A backup copy of the raw data will be also in a cloud-based backup server. Tables containing the raw data (output of the measurements) will be also included in the study report and shared with the study Sponsor by a pdf file electronically signed. The raw data will be stored for a minimum period of 10 years in Complife servers. In the raw data tables, subjects are identified by a means of a code generated by the Complife volunteer's management software. The code is composed of a letter, 4 digits, and a letter. The access to the study raw data is allowed only to the study director and the person designated by him to elaborate the raw data. Elaboration of the raw data includes descriptive statistics (mean and standard error) and the inferential analysis (data normality and statistical test).

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/04/2021	13/08/2021	Yes	No
Protocol file	version v1	06/07/2018	06/03/2020	No	No