Study Identification

Protocol ID: ATOP_PRO.4

Brief Title

“Clinical trial to evaluate a probiotic preparation efficacy in patients between 3 and 17 years old with atopic dermatitis”

Official Title

“Randomized, double-blind, placebo-controlled clinical trial to evaluate a probiotic preparation efficacy as adjuvant treatment in patients between 3 and 17 years old with atopic dermatitis”

Study Status

Study Start: 15/05/2023.

Study Completion: 15/05/2024

Sponsor/Collaborators

Sponsor: Galenicum Derma S.L

Collaborators: Grupo MiBioPath UCAM

Ethics Committee

Board Affiliation: Vinalopo University Hospital

Approval number: 26/10/2022

Study Description

Brief Summary

Randomized, double-blind, placebo-controlled clinical trial, to evaluate an oral probiotic effectiveness administered as adjuvant treatment for 12 weeks on the atopic dermatitis evolution in patients between 3 and 17 years old

Keywords: atopic dermatitis, atopic eczema, probiotics, microbiota, microbiome

Description

Randomized, double-blind, placebo-controlled clinical trial, to evaluate a probiotic preparation efficacy administered for 12 weeks on the evolution of atopic dermatitis patients between 3 and 17 years old

A total of 60 patients diagnosed with atopic dermatitis will participate in the study, who will be randomized into two treatment groups in a 1:1 ratio (30 patients per group).

The intervention groups are differentiated according to the treatment to be received: probiotic or placebo of similar appearance, along with standard therapy according to clinical guidelines.

The 12 weeks of treatment are structured into 4 face-to-face visits: Visit 1 (initial; week 0), Visit 2 (week 4), Visit 3 (week 8) and Visit 4 (final; week 12).

Study Design

Study type: Interventional

Interventional Study Model: Randomized, double-blind, placebo-controlled with parallel assignment

Number of arms: 2

Masking: Double (Participant and Investigator)

Allocation: Randomized

Enrollment: 60 patients

Arms and Interventions

Experimental arm

Probiotic group: Probiotic mixture of Lactobacillus and Bifidobacteria strains in oral capsule format. Freeze-dried probiotic at a minimum concentration of $1x10^9$ colony forming units (cfu), based on maltodextrin. Oral capsule consumption once a day for 12 weeks

Placebo comparator

Placebo group: Based on maltodextrin, in the same format as the probiotic. Oral capsule consumption once a day for 12 weeks

Outcome measures

Primary Outcome Measure

- Changes from baseline in SCORAD index at 4, 8 and 12 weeks

Secondary Outcome Measures

- Number of days that each patient requires the administration of topical corticosteroids during the 12-week follow-up
- Number of days that each patient requires the administration of topical corticosteroids in outbreaks of the disease during the 12-week follow-up
- Number of days that each patient requires the administration of antihistamines during the 12-week follow-up
- Changes from baseline in Clinical Global Impression (CGI) scale at 4, 8 and 12 weeks

- Changes from baseline in PIQoL-AD questionnaire at 4, 8 and 12 weeks
- Study treatment compliance rate at 4, 8 and 12 weeks
- Number of adverse events at 4, 8 and 12 weeks

Eligibility

Inclusion Criteria

• Patients diagnosed with atopic dermatitis according to the Hanifin and Rajka criteria.

• Patients with a SCORAD index of 20 to 40, both inclusive.

• Patients of both sexes with an age between 3 and 17 years.

• Patients who sign the informed consent in its two modalities: under or over 12 years of age.

• Signature of the Informed Consent by the Parents/Legal Guardian.

Exclusion Criteria

• Patients undergoing treatment with phototherapy for atopic dermatitis.

• Patients under treatment with systemic corticosteroids in the previous two months.

• Patients on treatment with immunosuppressants or cytostatics in the previous two months.

• Patients who have received treatment with probiotics in the previous two months.

• Patients with intolerance to any of the compounds present in the product.

• Patients who have been treated with systemic antibiotics in the previous four days.

• Patients with fever (axillary temperature or equivalent greater than 37.5 °C).

• Patients with severe allergic diseases.

• Patients with other dermatological pathologies that may make it difficult to assess atopic dermatitis or require the continued use of topical corticosteroids.

• Patients who have participated in other research studies within 30 days prior to the start of the study and/or during participation in the study.

• Breastfeeding.

• Women of childbearing age who do not commit to use any effective contraceptive method, in the investigator's judgment, if they are sexually active or initiate during the trial.

• Any other tumor pathology, pathological situations such as inflammatory bowel disease, pseudomembranous colitis, diverticulitis, cytomegalovirus colitis and, in general, any intestinal pathology that, in the researchers' opinion, implies intestinal bacterial dysbiosis.

• Any dermatological disease other than atopic dermatitis that involves an alteration of the skin microbiota such as any other type of skin cancer, acne, psoriasis, rosacea or chronic wounds associated with age.

Withdrawal Criteria

- Loss of tracking

- Withdrawal of consent

- Lack of collaboration

- Substantial changes during the study in the treatments, especially patients who are indicated to administer systemic corticosteroids, immunomodulators or biological drugs

- Any pathological situation that develops during the study and at the investigator's discretion does not allow it to continue in the same

- Suffering an Adverse Event that prevents them from performing the study procedures or complying with the study treatments.

- Use of other probiotics during the study

- Treatment adherence less than 80%

Contacts

Central Contact Person

Juan Gabriel Agüera Santos

Telephone: +34696807064

E-mail: juangabrielaguera@gmail.com

Locations

Vinalopo University Hospital

Elche, Alicante, Spain

Contact: Gonzalo Ros Cervera

E-mail: gonzalo.ros@gmail.com

Catholic University of Murcia (UCAM). MiBioPath Research Group

Murcia, Spain

Contact: Pedro Sánchez Pellicer

E-mail: pedro.sanchez@bioithas.com