Study Identification

Protocol ID: HS. PROB

Brief Title

“Clinical trial to evaluate the efficacy of an oral probiotic in hidradenitis suppurativa treatment”

Official Title

“Randomized, double-blind, placebo-controlled clinical trial to evaluate the efficacy of an oral probiotic preparation in hidradenitis suppurativa treatment”

Study Status

Study Start: 13/06/2023.

Study Completion: 13/06/2024

Sponsor/Collaborators

Sponsor: Galenicum Derma S.L

Collaborators: Grupo MiBioPath UCAM

Ethics Committee

Board Affiliation: University Hospital Fundación Jiménez Díaz

Approval number: 11/04/2023

Study Description

Brief Summary

The clinical trial has a randomized, double-blind, placebo-controlled design, which aims to evaluate the effect of an oral probiotic preparation administered for 12 weeks on the evolution of hidradenitis suppurativa.

Keywords: hidradenitis suppurativa, acne inversa, probiotics, microbiota, microbiome

Description

Randomized, double-blind, placebo-controlled clinical trial, to evaluate an oral probiotic effectiveness administered for 12 weeks on the hidradenitis suppurativa evolution.

A total of 60 patients diagnosed with hidradenitis suppurativa 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 usual clinical practice.

The 12 weeks of treatment are structured into three face-to-face visits: Visit 1 (initial; week 0), Visit 2 (intermediate; week 6) and Visit 3 (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 microcrystalline cellulose, in a hydroxy-propyl-methyl cellulose capsule. Oral capsule consumption once a day for 12 weeks

Placebo comparator

Placebo group: Based on microcrystalline cellulose, in a hydroxy-propyl-methyl cellulose capsule. Oral capsule consumption once a day for 12 weeks

Outcome measures

Primary Outcome Measure

- Changes from baseline in Hidradenitis Suppurativa Score (HSS) at 6 and 12 weeks

Secondary Outcome Measures

- Changes from baseline in Hidradenitis Suppurativa Physician's Global Assessment (HS-PGA) category at 6 and 12 weeks
- Hidradenitis Suppurativa Clinical Response (HiSCR) treatment response rate at 6 and 12 weeks
- Treatment response rate according to Canoui-Poitrine phenotypes at 6 and 12 weeks
- Changes from baseline in *Dermatology Life Quality Index* (DLQI) at 6 and 12 weeks

- Changes from baseline in Visual Analogue Scale (VAS) of the most painful injury at 6 and 12 weeks
- Changes from baseline in number, location and type of injuries accumulated between visits at 6 and 12 weeks
- Number and days of rescue treatments, as well as concomitant treatments at 6 and 12 weeks
- Changes from baseline in blood count and biochemistry values related to metabolic syndrome, insulin resistance, and inflammatory biomarkers at 12 weeks
- Changes in gut microbiota: alpha diversity, beta diversity and composition, by sequencing of the R16s gene, of a stool sample at baseline and 12 weeks
- Study treatment compliance rate at 6 and 12 weeks
- Number of adverse events at 6 and 12 weeks

Eligibility

Inclusion Criteria

- Patients of both sexes of an age equal to or greater than 18 years.

- Clinical diagnosis of Hidradenitis Suppurativa with at least one active lesion per month, defined as a painful nodule, sinus, abscess or fistula drainage, during the three months prior to the study.

- Patients with a new diagnosis or with stable treatment during the 8 weeks prior to inclusion in the study

- Patients who agree to comply with the established procedures and to give their written consent after receiving the information

Exclusion Criteria

- Pregnancy and lactation or who do not commit to use an effective contraceptive method during the course of the study

- Allergy and/or intolerance to any of the components of the product under study.

- Use of probiotics or antibiotics in the last 8 weeks

- Changes in the treatments commonly used for HS in the last 8 weeks

- Any pathological situation 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.

- Medical or surgical history that, at the investigator's discretion, does not allow participation in the study.

- Patients with fever (axillary temperature or equivalent higher than 37.5 °C).

- Patients with severe allergic diseases

- Refusal to participate in the study and to sign the consent.

- Who are participating or have completed their participation in another clinical trial with a drug or medical device in the last 30 days before the start of the study treatment.

Withdrawal Criteria

- Loss of tracking

- Withdrawal of consent

- Lack of collaboration

- Substantial changes during the study in the treatments habitually used by the patient before the start of the study, especially the cycles of systemic antibiotics lasting more than 7 days

- 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

University Hospital Fundación Jiménez Díaz

Madrid, Spain

Contact: Daniella Cullen Aravena

E-mail: dcullen@quironsalud.es