Targeted Investigation of Microbiome 2 Treat Atopic Dermatitis (TIME-2)

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 6 years and over
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria:

Each individual must meet all of the following criteria at Screening to be eligible for enrollment as a study participant:

1. Participant and/or parent/legal guardian must be able to understand and provide informed consent and assent (if applicable).
2. Male or female participant 6 years of age or older.
3. Meet ADRN Standard Diagnostic Criteria for active AD.

Each individual must meet all of the following criteria at Baseline to be eligible for enrollment as a study participant:
4. Have at least 7 cm2 of lesional skin within the upper extremities, lower extremities, and/or trunk. Lesions on the face, neck, hands, feet, and intertriginous areas do not count toward the required area, as samples may not be taken from these areas. The required area may be one contiguous area or may be comprised of multiple areas with a compliant total area.
5. Have at least 3% body surface area of AD involvement as indicated by derived total area of involvement score during SCORAD assessment.
6. Have an IGA score of two or greater.
7. Each potential participant who can become pregnant must meet either of the following criteria prior to randomization to be eligible for enrollment as a study participant.

1. Willing to remain abstinent from intercourse that may result in a pregnancy.
2. Willing to use an FDA-approved method of contraception for the duration of study participation. Acceptable methods include the following:

* Permanent sterilization of partner
* Long-acting reversible contraceptives (e.g., intrauterine devices or systems, implantable rods, contraceptive injections) when used as directed for at least 7 da ys prior to Baseline.
* Short-acting hormonal contraceptives (e.g., oral contraceptive pills, patch, vaginal ring) when used as directed for at least 30 days prior to Baseline
* Barrier methods (e.g., condoms; diaphragm, sponge, or cervical cap with spermicide)

1. Have obtained negative pregnancy test results during both the Screening and Baseline Visits.

Exclusion Criteria:

Individuals who meet any of the following criteria at Screening or Baseline are not eligible for enrollment as study participants:

1. Inability or unwillingness to give written informed consent or comply with study protocol.
2. Has self-reported as pregnant or lactating during the Screening or Baseline Visit, or is pregnant as indicated by a positive pregnancy test result obtained at the Screening or Baseline Visit.
3. Sensitivity to or difficulty tolerating Dove® fragrance-free bar soap, Cetaphil® lotion, alcohol-based cleaners, clobetasol and fluocinonide ointments, triamcinolone ointment, hydrocortisone ointment, glycerol, hydroxyethylcellulose or soy products.
4. Known recalcitrance to topical steroids, including class 1 steroids, within 6 months of the Screening Visit.
5. History of serious life-threatening reaction to tape or adhesives.
6. Known allergy to all antibiotics to which S. hominis A9 is sensitive. These include ampicillin-sulbactam, cefazolin, cefoxitin, clindamycin, daptomycin, doxycycline, levofloxacin, linezolid, minocycline, moxifloxacin, mupirocin, nitrofurantoin, oxacillin, rifampin, trimethoprim-sulfamethoxazole, and vancomycin.
7. Has a major defect in the epidermal barrier such as open wounds or genodermatoses (e.g., Netherton's syndrome).
8. Is immunocompromised (e.g., Human Immunodeficiency Virus (HIV)/Acquired Immunodeficiency Syndrome (AIDS), Wiskott-Aldrich Syndrome) or has an immune system disorder (e.g., autoimmune disease).
9. Has current malignant disease (except non-melanoma skin cancer in an area not affected by treatment).
10. Has a history of psychiatric disease or history of alcohol or drug abuse that, in the opinion of the study investigator, would interfere with the ability to comply with the study protocol.
11. Ongoing participation in another investigational trial or use of investigational drugs within 8 weeks, or five half-lives (if known), whichever is longer, of the Screening Visit.
12. Treatment with non-steroid systemic immunosuppressant within 6 months of the Screening Visit.
13. Treatment with any biologic, including dupilumab, within 16 weeks of the Screening Visit.
14. Treatment with oral or injectable therapy for AD (excluding oral steroids) within five half-lives (if known) or 16 weeks before the Screening Visit, whichever is longer.
15. Treatment with oral retinoids (e.g., isotretinoin) within 60 days of the Screening Visit.
16. Treatment with allergen immunotherapy within 30 days of Screening Visit.
17. Has close contacts (e.g., spouse, children, or members in the same household) who have severe barrier defects or are immunocompromised.
18. May, in the opinion of the investigator, have difficulty tolerating the medication washout requirements for topical AD treatments, prescription moisturizers, antibiotics, oral steroid therapies, and phototherapy ahead of Baseline.
19. Past or current medical conditions or findings from physical examination or laboratory testing that are not listed above, which, in the opinion of the investigator, may pose additional risks from participation in the study, may interfere with the participant's ability to comply with study

requirements or that may impact the quality or interpretation of the data obtained from the study.

Individuals who meet any of the following criteria at Baseline are not eligible for enrollment as study participants:

20. Have more than 30% body surface area of AD involvement, as indicated by the derived total area of involvement score during SCORAD assessment.
21. Active bacterial, viral, or fungal skin infections, except for onychomycosis and tinea pedis.
22. Any noticeable breaks or cracks in the skin on the target areas of investigational product application, including severely excoriated skin or skin with open or weeping wounds suggestive of an active infection.

    a. At the investigator's discretion, participants with minor breaks, cracks, or excoriations on body areas not eligible for sampling during the trial may be enrolled, provided there is no evidence of infection and investigational product is not applied to these areas until healed.
23. Use of topical AD treatments - including steroids and calcineurin inhibitors - on the upper extremities (exclusive of the hands), lower extremities (exclusive of the feet), or trunk within seven days of the Baseline Visit.
24. Treatment with prescription moisturizers classified as medical device (e.g., Atopiclair®, MimyX®, Epiceram®, etc.) on the upper extremities (exclusive of the hands), lower extremities (exclusive of the feet), or trunk within seven days of the Baseline Visit.
25. Use of any systemic microbial[a] within fourteen days of the Baseline Visit, or use of any topical antimicrobial on the upper extremities (exclusive of the hands), lower extremities (exclusive of the feet), or trunk within fourteen days of the Baseline Visit.

    a. Antimicrobials include antibiotics, antifungals, antiparasitics, and antivirals. Certain systemic antivirals that do not exhibit systemic anti-inflammatory effects may be permitted with prior approval from a protocol co-chair).
26. Within the upper extremities (exclusive of the hands), lower extremities (exclusive of the feet), and trunk, use of topical products - prescription or over-the-counter, all formulations - not specified per protocol, within seven days of the Baseline Visit.
27. Use of systemic corticosteroid therapies for any indication within 28 days of the Baseline Visit.
28. Use of systemic corticosteroid therapies for treatment of an asthma exacerbation within 3 months of the Baseline Visit.
29. Require a dose greater than 880 mcg/day of fluticasone propionate or equivalent inhaled corticosteroid to maintain asthma control, at the time of the Baseline Visit.
30. Any phototherapy for skin disease (such as narrow band ultraviolet B [NBUVB], ultraviolet B [UVB], ultraviolet A1 [UVA1], psoralen + UVA [PUVA]) or regular use (more than 2 visits per week) of a tanning bed within 28 days of the Baseline Visit.

Conditions & Interventions

Interventions:
DRUG: ShA9 Topical Gel, DRUG: Hydrocortisone Ointment, DRUG: Clobetasol Ointment, DRUG: Fluocinonide Ointment, DRUG: Placebo (Vehicle) Topical Gel, DRUG: Triamcinolone Ointment
Conditions:
Atopic Dermatitis
Keywords:
atopic dermatitis, eczema, ADRN, TIME-2, microbiome, Staphylococcus hominis

More Information

Description:
This is a Phase 1b, randomized, placebo/vehicle-controlled, double-blinded, multi-center trial. It is designed to assess the safety and efficacy of S. hominis A9 (ShA9) topical application as a treatment for atopic dermatitis (AD). The trial will enroll adults and pediatric participants with atopic dermatitis. The primary safety objective of this study is to compare the safety profile of ShA9 to placebo (vehicle) over 14 weeks of application, which includes an initial two-week period of co-treatment with topical corticosteroids (TCS). The primary efficacy objective of this study is to assess the ability of ShA9, compared to placebo (vehicle), to prolong the period of atopic dermatitis control over 12 weeks after conclusion of an initial two-week period of co-treatment with TCS.

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