

Randomized Study Using SM-030 Gel for Adults With Melasma

NCT06454747

Status	RECRUITING
Phase	Phase 2
Sponsor	DermBiont, Inc.
Enrollment	138 participants

Key Eligibility Criteria

Inclusion (9)

- Subjects must meet all of the following criteria to be included in the study:
- Subjects must meet all of the following criteria to be included in the study:
- Male or Female age 18-65 with Fitzpatrick skin type II through V and a clinical diagnosis of Melasma
- Subjects with moderate to severe Melasma using the following guidelines:
 1. Stable (unchanged per subject reporting) melasma for at least 3 months
 2. Macular lesions, neither depressed nor atrophic
 3. Melasma Severity Score of at least 2 (hyperpigmentation at least moderately darker than surrounding normal skin)
 3. Ability to understand, agree to, and sign the study informed consent form (ICF).

... and 4 more (see full listing online)

Exclusion (19)

- Subjects who meet any of the following criteria will be excluded in the study:
- Positive urine pregnancy test, pregnant, lactating, or female of childbearing potential who does not agree to use an active method of birth control for the duration of the study.
- Conditions at baseline that would interfere with evaluation of UV-tanned skin, especially other pigmentary disorders including, but not limited to vitiligo affecting the treatment and comparison sites.
- Severe photodamage as assessed by the 10-point photo damage assessment scale (Griffiths et al., 1992); (McKenzie et al., 2011).
- Presence of known concomitant diseases associated with the development of hyperpigmentation (e.g., thyroid, liver, adrenal).

... and 14 more (see full listing online)

Locations (2 total)

Zepeda Dermatologia, Santa Tecla, La Libertad Department, El Salvador

Centro de Investigación y Desarrollo Briosó Ramirez, Santa Tecla, La Libertad, El Salvador, El Salvador

<https://clinicaltrials.gov/study/NCT06454747>

DISCLAIMER: This document is for informational purposes only and does not constitute medical advice. Always consult your healthcare provider before enrolling in any clinical trial. Information may not be up to date — verify details at [ClinicalTrials.gov](https://clinicaltrials.gov). Generated by [ClinicalTrialsFinder.org](https://clinicaltrialsfinder.org).