

Arnica Tincture For the Treatment of Cutaneous Leishmaniasis II.

NCT06822478

Status	RECRUITING
Phase	Phase 3
Sponsor	Universidad de Antioquia
Enrollment	96 participants

Key Eligibility Criteria

Inclusion (2)

- \. Males or females, over 12 years of age and adults without age limit. With a confirmed parasitological diagnosis of a primary infection of LC in at least one lesion, made by one of the following methods: 1) microscopic identification of amastigotes in the lesion tissue; 2) diagnosis of leishmania by PCR; 3) positive culture for promastigotes (Annex 2).
- \. With clinical diagnosis of localized LC. 4. Ulcer, nodule or plaque type lesions. Up to 9 lesions in total, and that the total area of all lesions is $\leq 1875 \text{ mm}^2$. 6. Subjects who have given written IC/Assent. 7. Subject is able to understand and comply with the requirements of the study. 8. Subjects who are able to attend the control visits.

Exclusion (8)

- Participants presenting one or more of the following criteria should be excluded from the study:
- Diagnosis or suspicion of mucosal/mucocutaneous, diffuse or disseminated Leishmaniasis or relapse or reactivation of an LC.
- Subjects with lesions involving the auricular region, orbital region, nasal region and/or labial region of the face, joints or in places that, in the opinion of the investigator, are difficult to apply topically or intralesionally to the study medication.
- History of clinically significant cardiovascular, renal, hepatic, hepatic, neurological or immunological diseases that may interact positively or negatively with the treatment.
- Having received treatment for Leishmaniasis or other treatment that, in the judgment of the investigator, may modify the course of infection with Leishmania in the last 8 weeks (56 days) prior to admission.

... and 3 more (see full listing online)

Locations (1 total)

Grupo de Investigación Clínica PECET (GIC-PECET), Medellín, Antioquia, Colombia