A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study to Investigate the Efficacy and Safety of Oral Brepocitinib in Adults with Dermatomyositis

Status: Recruiting

Eligibility Criteria

Sex: Male or Female
Age Group: 18 years and over
This study is NOT accepting healthy volunteers

Inclusion Criteria:

1. diagnosis of dermatomyositis 2. active muscle and skin disease or being treated with medications 3. age 18-75 4. weight at least 40 kg, less than 130 kg and a BMI less than 40 kg/m2

Exclusion Criteria:

1. history of cancer in past 5 years 2. dermatomyositis with irreversible muscle involvement 3. active or recent infections

Conditions & Interventions

Interventions:
Drug: Brepocitinib, Drug: Placebo
Conditions:
Arthritis & Rheumatic Diseases, Dermatology (Skin, Hair & Nails)
Keywords:
Clinics and Surgery Center (CSC), dermatomyositis

More Information

Description: In this study, brepocitinib will be compared to a placebo. Brepocitinib is an investigational medicine because it has not yet been approved by any regulatory agency for use. Researchers will compare the results of taking the placebo to the results of taking the study medicine to see if there are any differences. This medicine may be helpful for your disease, but we do not have any information about this yet. 67% of participants will receive brepocitinib and 33% will receive the placebo which will be decided randomly by chance. Participation will last for up to 64 weeks (15 months). Visits will be scheduled about every 4 to 6 weeks.
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Phase: Phase III
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