A 6-Month Phase 3, Multicenter, Prospective, Randomized, Double-Blind, Vehicle-Controlled Study, to Evaluate the Efficacy and Safety of Topically Applied Clascoterone (Cortexolone 17A-Propionate) Solution for the Treatment of Androgenetic Alopecia in Males, Followed by a 6-Month Single-Blind Treatment with Clascoterone or Vehicle BID Solution. (SCALP 1)

Status: Recruiting

Eligibility Criteria

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

Inclusion Criteria:

- men who are 18 or older - have mild to moderate Androgenic Alopecia (AGA) in temple and top region of the scalp - willing to maintain the same hairstyle, hair length and hair color throughout the study - agree to continue shampoo frequency and other general hair care products and regimen for the entire study - agree to maintain same dietary and supplement pattern

Exclusion Criteria:

- any dermatological disorders at the temple or the top of the scalp - current or recent history (within 6 months) of hair weaves, non-breathable wigs, or hair bonding - scalp hair transplants at any time - see link to clinicaltrials.gov for additional exclusion criteria (study staff will review)

Conditions & Interventions

Conditions:
Dermatology (Skin, Hair & Nails)
Keywords:
Clinics and Surgery Center (CSC), Alopecia, Androgenetic Alopecia, Male Alopecia, AGA

More Information

Description: We are studying a new topical drug, Clascoternone, to treat adult males who have male pattern baldness. Participants randomly (by chance) receive the drug or an inactive solution that is applied to the area of hair loss twice a day for six months. We will compare the effectiveness and side effects of the two groups. Men who have regrowth of hair may also participate in a second six-month treatment to look at the long-term effectiveness of the drug.
Study Contact: Gretchen Bellefeuille - belle116@umn.edu
Principal Investigator: Maria Hordinsky
IRB Number: SITE00002038