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A study testing whether a new conditioner used with ketoconazole shampoo improves hair health and scalp symptoms in people with dandruff (seborrheic dermatitis) compared to using the shampoo alone

Submission date
05/09/2025

Recruitment status
Recruiting

Registration date
30/09/2025

Overall study status
Ongoing

Last Edited
08/09/2025

Condition category
Skin and Connective Tissue Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Seborrheic dermatitis is a common scalp condition that causes dandruff, itching, redness, and flaking. Ketoconazole shampoo is an effective treatment but can sometimes make hair dry or brittle. This study aims to find out whether adding a conditioner specially developed to be used with ketoconazole shampoo can improve hair hydration, hair texture, and overall scalp health compared to using the shampoo alone.

Who can participate?
Adults aged 18–65 years with mild to severe seborrheic dermatitis of the scalp, at least 5 cm of hair length, in good general health, and willing to follow study instructions. Participants must not be pregnant or breastfeeding and must agree not to use other hair or scalp treatments during the study.

What does the study involve?
A total of 66 participants will be randomly assigned to one of two groups: one group will use ketoconazole shampoo plus conditioner, and the other group will use ketoconazole shampoo alone. Products will be used twice per week for 28 days. Each participant will attend five visits at the study site (on days 0, 7, 14, 21, and 28). Doctors will assess hair hydration, hair texture, scalp condition, and symptoms. Participants will also complete questionnaires on quality of life, symptoms, and satisfaction with the products.

What are the possible benefits and risks of participating?
Participants may experience improvement in scalp condition and hair health. Risks are expected to be low as the products are already marketed, but there is a small chance of local irritation, allergic reaction, or intolerance.

Where is the study run from?
CIDP Ltée (Mauritius)

When is the study starting and how long is it expected to run for?
August 2025 to June 2026

Who is funding the study?
STADA Arzneimittel AG (Germany)

Who is the main contact?
Dr Gitanjali Petkar, g.petkar@cidp-cro.com

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil Known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CT-38014-25-0287

Study information

Scientific Title
A Phase IV, randomized, single-blinded study to evaluate the efficacy and safety of ketoconazole 2% shampoo + conditioner vs ketoconazole 2% shampoo alone in adults with seborrheic dermatitis

Acronym
K-SCSD

Study objectives
1. To evaluate the improvement in hair hydration and hair texture after application of Ketoconazole 2% Shampoo + Conditioner compared to Ketoconazole 2% Shampoo alone.
2. To evaluate the improvement in the clinical presentation of seborrheic dermatitis.
3. To evaluate the improvement in scalp hydration.
4. To evaluate the improvement in participants' quality of life.
5. To illustrate qualitatively the efficacy of the products.
6. To assess the cosmetic acceptability and tolerance of the products following use.

Ethics approval required
Ethics approval required

Ethics approval(s)
submitted 06/08/2025, Clinical Research Regulatory Council (CRRC) (Level 2, Nexsky Building, Ebene, Ebene, 72201, Mauritius; +230 (0)57401165; v.kolanthan@cidp-cro.com), ref: 2324CMCL134

Study design

Interventional Phase IV randomized single-blinded controlled parallel-group trial

Primary study design
Interventional

Study type(s)
Quality of life, Safety, Efficacy

Health condition(s) or problem(s) studied
Seborrheic dermatitis (SD)

Interventions
The order of receiving the investigational product for each participant will be determined according to a randomization schedule. Participants will be randomized to one of the two groups to receive either Ketoconazole 2% Shampoo plus Conditioner or Ketoconazole 2% Shampoo alone. The randomization schedule will be generated by CIDP's biostatistician by using SAS® statistical software (Version: 9.4 or higher; SAS Institute Inc., USA).

The randomization schedule will be maintained under controlled access. The personnel involved in the dispensing of investigational products will be accountable for ensuring compliance to the randomization schedule. All other staff will not have access to the randomization schedule during the course of analysis in order to minimize/ avoid bias.

Apart from the personnel involved in the dispensing of IP all other staff (incl. the investigators) will be blinded and participants will be instructed not to disclose their treatment (shampoo only or shampoo + conditioner).

Arm 1 (Test): Ketoconazole 2% Shampoo (Terzolin® 2% Solution) + Terzolin® Expert Conditioner (Nizoral Anti-Dandruff Daily Prevent Conditioner in UK market).

Arm 2 (Comparator): Ketoconazole 2% Shampoo (Terzolin® 2% Solution) alone

Products will be used twice per week for 28 days. Each participant will attend five visits at the study site (on days 0, 7, 14, 21, and 28). Doctors will assess hair hydration, hair texture, scalp condition, and symptoms. Participants will also complete questionnaires on quality of life, symptoms, and satisfaction with the products.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Ketoconazole 2% Shampoo, Terzolin® 2% Solution (Germany); Terzolin® Expert Conditioner (Germany), Equivalent UK brand: Nizoral Anti-Dandruff Daily Prevent Conditioner

Primary outcome(s)

1. Hair hydration measured by dermatologist Visual Analogue Scale (VAS), gravimetric hair measurements, and participant self-evaluation from baseline (Day 0) to Day 28
2. Hair texture measured by dermatologist Visual Analogue Scale (VAS) and participant self-evaluation. from baseline (Day 0) to Day 28

Key secondary outcome(s))
1. Seborrheic dermatitis symptoms from baseline to Day 28, measured by:
1.1. Symptoms Scale of Seborrheic Dermatitis (SSSD) at Days 0, 14, and 28
1.2. Total Scale Scores (TSS) at Days 0, 14, and 28
2. Pruritus severity measured using Numeric Rating Scale (NRS, 0–10) at Days 0, 14, and 28
3. Erythema measured using Visual Analogue Scale (VAS, 0–10) at Days 0, 14, and 28
4. Scalp greasiness measured using Visual Analogue Scale (VAS, 0–10) at Days 0, 14, and 28
5. Scalp hydration measured by Corneometer® readings at Days 0, 7, 14, 21, and 28
6. Quality of life measured by Scalpdex questionnaire at Days 0, 14, and 28
7. Cosmetic acceptability of products assessed by participant self-evaluation questionnaires (cosmeticity, acceptability, efficacy, global satisfaction) at Days 14 and 28
8. Safety and tolerance of products assessed by incidence of local intolerances and adverse events throughout the study (Day 0–28)

Completion date
05/06/2026

Eligibility

Key inclusion criteria
1. Males and females aged 18-65 years
2. Participants presenting a minimum hair length of 5 cm and agreeing to this criterion during the entire study period
3. Participants with mild to severe Seborrheic Dermatitis on the scalp
4. Participants presenting with all scalp types
5. Participants presenting with all hair type
6. Non-pregnant and non-breastfeeding participants
7. Participants having received the information about the study modalities and having given his /her written consent and having signed the informed consent form specific for this study, in accordance with the corresponding procedure
8. Participants usual users of shampoo two times a week and accepting to follow a rate of two times a week during the whole study period
9. Participantls agreeing not to use any other hair product other than the ones provided for the study (till the end of study); in particular:
9.1. Three days before the study visit, no styling products (e.g. tonic, spray, lotion, foam, gel, wax, etc)
9.2. No treating haircare products (conditioner, hair mask, non-rinsed hair care product, oil)
9.3. No anti-scales products (whatever the type: shampoo, treatment); no hair colouring or hair bleaching within one week prior to any study visit
10. Participants in good general and mental health in the opinion of the investigator
11. Participants demonstrating understanding of the study procedures, restrictions, and willingness to participate as evidenced by voluntary written informed consent and having received a signed and dated copy of the informed consent form
12. Participants who have agreed to comply with the procedures and requirements of the study and to attend the scheduled assessment visits

Participant type(s)
All

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Key exclusion criteria
1. Participants should not use of any anti-dandruff/SD/conditioning products (containing ketoconazole, selenium sulphide, coal tar etc) or any topical treatment (anti-fungals, corticosteroids, calcineurin inhibitors and salicylic acid) 2 weeks before the study.
2. Participants presenting with scalp psoriasis.
3. Participants suffering from any other scalp disorders e.g. bacterial folliculitis, tinea capitis, alopecia areata
4. Participants who have used topic treatment for the scalp (anti-hair loss, soothing) during the last 3 weeks before the start of the study.
5. Participants who have used products for the scalp (dyeing, bleaching, permanent waving and straightening) within the 3 weeks prior to the study
6. Participants with sensitivity and allergy to ketoconazole or other component
7. Pregnancy, breastfeeding, childbearing potential without adequate contraception, or irregular menstrual cycles
8. History or suspicion of unreliability, poor cooperation or noncompliance with medical treatment
9. Topical treatment of the scalp with other antifungal medication or with corticosteroids in the last 3 weeks before the start of the study
10. Participants with personal history of allergy and/or adverse reactions to cosmetic products containing surfactant agents (soaps, shower gel, conditioner)
11. Likelihood of requiring treatment during the study period with drugs not permitted by the study protocol
12. Clinical signs and/or history of immunosuppression
13. Severe disease (e.g. cancer, cardiac infarct, unstable angina pectoris
14. Treatment with any other investigational drug in the 4 weeks prior to study entry
15. Employee of the sponsor or the study site

Date of first enrolment
03/11/2025

Date of final enrolment
08/05/2026

Locations

Countries of recruitment
Mauritius

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CIDP Ltee
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Sponsor information

Organisation
STADA Arzneimittel AG

Funder(s)

Funder type
Industry

Funder Name
STADA Arzneimittel AG

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from CIDP.

IPD sharing plan summary
Available on request