ISRCTN79977393 https://doi.org/10.1186/ISRCTN79977393

The ability of anti-dandruff shampoo to reduce dandruff, itching, scalp histamine, and scalp microbiome in subjects with moderate to severe dandruff

Submission date
17/11/2024

Recruitment status
No longer recruiting

Registration date
27/11/2024

Overall study status
Completed

Last Edited
26/11/2024

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
Dandruff is a common chronic scalp condition that affects more than half of the world's population and has been known since antiquity. Despite its high prevalence, the exact pathophysiology is not well established and is understood to be multifactorial, with factors such as fungal colonization, sebaceous gland activity, and individual factors being implicated. There is a need for an effective and safe shampoo that can target the above factors. The aim of this study is comparing the effects of an anti-dandruff shampoo containing selenium sulfide with a shampoo containing selenium sulfide and piroctone olamine on dandruff, itching, histamine levels or inflammatory markers, and the scalp microbiome in subjects with moderate to severe dandruff.

Who can participate?
The participants of this study are healthy males and females aged 18-65 years old who had not undergone menopause (female) with moderate to severe dandruff.

What does the study involve?
Participants would be instructed to use the randomly assigned shampoo three times a week. Scalp dandruff and itching will be measured at baseline, day 14, and 28. Scalp histamine levels or inflammation markers and scalp microbiome will be measured at baseline and day 28.

What are the possible benefits and risks of participating?
The possible benefits are shampoo and laboratory tests to determine the severity of dandruff, histamine levels or inflammatory markers, and the condition of the microbiome on the scalp, while the risks are a feeling of burning, stinging or pain, accompanied by changes to the scalp in the form of redness, pimples, lumps and/ or discharge.

Where is the study run from?
Faculty of Medicine, Universitas Kristen Duta Wacana (Indonesia).

When is the study starting and how long is it expected to run for?
July 2024 to February 2025

Who is funding the study?
Rohto Mentholatum (Vietnam) Co., Ltd.

Who is the main contact?
Arum Krismi, penelitian.arumkrismi@gmail.com

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
The effect of anti-dandruff shampoo on scalp dandruff, itch, histamine, and microbiome

Study objectives

Anti-dandruff shampoo could reduce dandruff, itch, histamine levels, and improve scalp microbiome

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 15/10/2024, Health Research Ethics Committee of Faculty of Medicine, Universitas Kristen Duta Wacana (GEDUNG KOINONIA Jl. Dr. Wahidin Sudirohusodo 5-25 Kotabaru, Gondokusuman, Yogyakarta, 55224, Indonesia; +62 89511803304; kepk@staff.ukdw.ac.id), ref: 1663/C.16/FK/2O24

Study design
Single-centre interventional double-blinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
University/medical school/dental school

Study type(s)
Treatment

Participant information sheet
See outputs table

Health condition(s) or problem(s) studied
Moderate to severe dandruff

Interventions
Interventions: anti-dandruff shampoo containing selenium sulfide, selenium sulfide and piroctone olamine, and placebo
Randomization: simple randomization
Details of interventions: Shampooing 3 times a week with one of the products, about 10 mL shampoo on every shampooing, for 4 weeks

Intervention Type
Other

Primary outcome measure
Scalp dandruff measured using Adherent Scalp Flaking Score (ASFS) at baseline, day 14, and 28

Secondary outcome measures
1. Itch intensity measured using Worst Itching Intensity-Numerical Rating Scale (WI-NRS) at baseline, day 14, and 28
2. Scalp histamine levels or inflammation markers measured using ELISA at baseline and day 28

3. Scalp microbiome measured using Nanopore® Next Generation Sequencer at baseline and day 28

Overall study start date
01/07/2024

Completion date
28/02/2025

Eligibility

Key inclusion criteria
1. Had not undergone menopause for female
2. Have Adherent Scalp Flaking Score (ASFS) of ≥ 24 at the baseline visit
3. Comply with the procedure, agree to complete the study, and provide written informed consent

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
99

Key exclusion criteria
1. Having scalp diseases or scalp scarring
2. Having history of contact dermatitis at the scalp
3. Having difficulties in verbal and written communication
4. Having difficulties in mobility
5. Using medication of oral anti-fungal, immunosuppressant agents, anti-inflammatory, or chronic antihistamine drugs within 4 weeks prior to baseline
6. Using medication of anti-dandruff, anti-psoriatic, or anti-seborrhoeic dermatitis shampoos within 2 weeks prior to baseline; and any other significant medical condition

Date of first enrolment
07/12/2024

Date of final enrolment
11/01/2025

Locations

Countries of recruitment
Indonesia

Study participating centre
Faculty of Medicine, Universitas Kristen Duta Wacana
Gedung Logos
Jl. Dr. Wahidin Sudirohusodo no. 5-25, Kotabaru, Kel. Gondokusuman
Yogyakarta
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Sponsor information

Organisation
Faculty of Medicine, Universitas Kristen Duta Wacana

Sponsor details
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Sponsor type
University/education

Website
https://ukdw.ac.id/akademik/fakultas-kedokteran/pendidikan-dokter/

Funder(s)

Funder type
Industry

Funder Name
Rohto Mentholatum (Vietnam) Co., Ltd

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
30/09/2025

Individual participant data (IPD) sharing plan
The datasets generated and/ or analysed during the current study are/ will be available upon request from Arum Krismi (dr_arumkrismi@staff.ukdw.ac.id). The type of data will be shared as requested in the format of excel, when all of the results are already published for about 5 years since the end of the study, to view only, with other investigators of the same field of study (dandruff), without consent from participants because the data would not contain participants' identity except their age and sex.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		27/09/2024	26/11/2024	No	Yes