

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 27/11/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 26/11/2024	Condition category Skin and Connective Tissue Diseases	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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

Contact name

Dr Arum Krismi

ORCID ID

<http://orcid.org/0000-0003-4276-3025>

Contact details

Sekar Bakung Residence no. E1
Jl. Imogiri Barat, Semail, Kel. Bangunharjo, Kec. Sewon, Daerah Istimewa Yogyakarta
Bantul
Indonesia
55188
+62 811254861
dr_arumkrismi@staff.ukdw.ac.id

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/2024

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

Indonesia

55224

Sponsor information

Organisation

Faculty of Medicine, Universitas Kristen Duta Wacana

Sponsor details

Logos Building, 1st Floor

Jl. Dr. Wahidin Sudirohusodo no. 5-25, Kec. Kotabaru, Kel. Gondokusuman, Daerah Istimewa

Yogyakarta

Yogyakarta

Indonesia

55224

+62-274-563929 ext. 606; + 62-8289-2001-888

kedokteran@staff.ukdw.ac.id

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