

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

<b>Submission date</b> 17/11/2024	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 27/11/2024	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 26/11/2024	<b>Condition category</b> Skin and Connective Tissue Diseases	<input type="checkbox"/> Individual participant data <input 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

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

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

## **Study type(s)**

Treatment

## **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(s)**

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

## **Key secondary outcome(s)**

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

## **Completion date**

28/02/2025

## **Eligibility**

### **Key inclusion criteria**

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

**Participant type(s)**

Healthy volunteer

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Upper age limit**

65 years

**Sex**

All

**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

## Funder(s)

**Funder type**  
Industry

**Funder Name**  
Rohto Mentholatum (Vietnam) Co., Ltd

## Results and Publications

**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		Date created	Date added	Peer reviewed?	Patient-facing?
Output type	Details				
<a href="#">Participant information sheet</a>		27/09/2024	26/11/2024	No	Yes
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes