PARTICIPANT INFORMATION SHEET

Title	The ability of anti-dandruff shampoo to reduce dandruff, itching, scalp histamine, and scalp microbiome in subjects with moderate to severe dandruff
Study design	Single-centre interventional double-blinded randomized controlled trial
Investigators/ Institution	1. Arum Krismi (Principal Investigator)/ Faculty of Medicine, Universitas Kristen Duta Wacana 2. Sendy Junedi/ Faculty of Biotechnology, Universitas Atma Jaya Yogyakarta 3. Monika Puspitasari/ Faculty of Medicine, Universitas Kristen Duta Wacana 4. Felicia Hilary Lucy/ Faculty of Medicine, Universitas Kristen Duta Wacana

Research Contact
Arum Krismi
Faculty of Medicine, Duta Wacana Christian University
Telp: +62-811254861
Email: penelitian.arumkrismi@gmail.com

Complaints Contact
Health Research Ethics Committee
Faculty of Medicine, Universitas Kristen Duta Wacana
Koinonia Building
Jl. Wahidin Sudirohusodo 5-25 Yogyakarta, Indonesia 55224
Telp. +62-274-563929 ext.124, +62-8951-1803-304
e-mail: kepk@staff.ukdw.ac.id

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This information sheet contains important information to help you decide whether or not to participate in this study. The investigator will explain about this study to you. Ask questions about anything unclear at any time. You can take this information sheet home to think about and discuss with family, relatives or friends.

A. Introduction to the shampoo under study

Dandruff is a chronic scalp condition, which more than half of the world's population suffers from. This condition is characterized by a combination of flaking of the scalp, itching, and mild inflammation, both on oily and dry scalps. Peeling of the skin and itching can cause uncomfortable sensations throughout the day, thereby reducing the sufferer's quality of life and having a psychosocial impact in terms of cosmetics.

Selenium sulfide and piroctone olamine are often used as active ingredients in anti-dandruff shampoo because of their antifungal properties. These two substances are contained in several anti-dandruff shampoos on the market with different concentrations. Currently, there are few studies on the analysis of selenium sulfide shampoos for histamine levels or markers of

inflammation and scalp microbiome, and even fewer analyzes using shampoos containing selenium sulfide and piroctone olamine. The use of anti-dandruff shampoo containing selenium sulfide as well as a combination of selenium sulfide and piroctone olamine is expected to reduce dandruff, reduce histamine levels or inflammatory markers, and improve the scalp microbiome.

B. Aim of the study

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.

C. Study Procedure

This study requires 99 (ninety-nine) participants who will receive shampoo randomly. The duration of your participation in this study is 6 weeks. You will have to come to the research location 4 times on Day -14, 0, 14, and 28. During the study, you will receive 2 bottles of shampoo each weighing 100 g, either containing selenium sulfide, or selenium sulfide and piroctone olamine, or control shampoo, as described below.

Requirements for participating in this study

1. Male or female.
2. Age 18-65 years old.
3. Had not undergone menopause for female.
4. Comply with the procedure, agree to complete the study, and provide written informed consent.

You will not be able to participate in this study if

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 scalp condition.

If you meet the above criteria and have signed the informed consent, you will have have to come to the research location 4 times.

1. On the first visit (Day -14), the investigator will
   a. explain again the aims and procedures of the study, ensure that you have signed the consent form, and ensure that you can participate in the study
   b. assess the severity of dandruff on your scalp
   c. gives you a bottle of control shampoo that you should use three times a week (every Sunday, Tuesday, and Thursday) for 2 weeks (wash-out period)
2. On the second visit (Day 0), the investigator will
   a. assess the severity of dandruff on your scalp
   b. taking scalp surface samples using 2 methods, which will be used to determine histamine levels or inflammatory markers, and your scalp microbiome

c. ask your self-perception of the severity of dandruff and the level of itching on your scalp
d. randomly assign you into one of 3 (three) different groups to receive a shampoo containing selenium sulfide, or selenium sulfide and piroctone olamine, or a control shampoo, which you must use three times a week (every Sunday, Tuesday, and Thursday) for 2 weeks

3. On the third visit (Day 14), the investigator will
   a. assess the severity of dandruff on your scalp
   b. ask your self-perception of the severity of dandruff and the level of itching on your scalp
   c. ask you to fill out a questionnaire
   d. gives you a bottle of shampoo with the same ingredients as the one you received at the second visit, which you should use three times a week (every Sunday, Tuesday, and Thursday) for 2 weeks
4. On the last visit (Day 28), the investigator will
   a. assess the severity of dandruff on your scalp
   b. taking scalp surface samples using 2 methods, which will be used to determine histamine levels or inflammatory markers, and your scalp microbiome
   c. ask your self-perception of the severity of dandruff and the level of itching on your scalp
   d. ask you to fill out a questionnaire

D. Participant's Obligation

As a study participant, you are obliged to follow the study instructions as written above. If you have any questions, you can ask the research team to explain it to you. During the study, you are not allowed to use topical medications, herbal concoctions, special shampoos, hair oils, and/ or other products on your scalp.

E. Possible Side Effects

Shampoo with selenium sulfide and/ or piroctone olamine has so far do not had any significant side effects, but sometimes side effects can occur in some people. The most frequently observed complaints due to the use of the study shampoo are a feeling of burning, stinging or pain, accompanied by changes to the scalp in the form of redness, pimples, lumps and/ or discharge. If you experience any side effects, you are asked to immediately stop using the shampoo and contact the investigator as soon as possible, and inform the research team at the next meeting.

F. Possible Benefits from participating in the Study

The immediate benefit are shampoo and laboratory tests to determine the severity of dandruff, histamine levels or inflammatory markers, and the condition of the microbiome on your scalp.

G. Costs for participating in the Study

All study-related costs will be covered by the investigator.

H. Reimbursement for participating in the Study

You will receive transportation reimbursement of IDR 30,000 (thirty thousand rupiah) and a box of snack for each meeting. You will not receive any reimbursement for meetings you do not attend.

I. Compensation of Side Effects

If you experience any complaint that is suspected to be a possible side effect of using the study shampoo, your participation in this study may be terminated by the investigator, and you will receive compensation in the form of free consultation and treatment regarding your complaint for 2 weeks from the onset of the complaint, whether the complaint arose during the study or complaints that are suspected to be possible side effects of using the study shampoo which may still arise within a maximum period of 1 week after the study is completed.

J. Personal Information and Confidentiality of Study Records

All information regarding your personal identity will be kept confidential and will only be known to the research team. The research team will provide you a participant identity card that will not reveal your name, identity number, address or other personal data. Study results will be published without your personal identity.

K. Voluntary Participation/ Withdrawal

You are free to choose to participate in this study without coercion. If you have decided to participate, you are also free to withdraw/ change your mind at any time without being subject to any fines or consequences.

L. Early Termination of the Study

For your best interest or if you are unable to comply with the study procedures (for example, you are unable to attend the next meeting), the investigator may decide to terminate your participation in this study without your consent.

CONSENT FORM TO PARTICIPATE IN THE STUDY (INFORMED CONSENT)*

1. I : _____ Age : ____ years
   Address : _____
   Whatsapp no. : _____
   Declare willingness to participate in this study with the title: The ability of anti-dandruff shampoo to reduce dandruff, itching, scalp histamine, and scalp microbiome in subjects with moderate to severe dandruff
2. I declare that I have read and understand the "Participant Information Sheet" which contains information related to this study and the conditions for participating as a participant
3. I declare that the investigator has provided a verbal explanation to clarify matters related to the information mentioned above. I have understood it and have been given time to ask questions that are unclear
4. I realize that perhaps I will not directly receive or feel the benefits of this study, but it has been conveyed to me that the results of this study will be useful to determine the ability of anti-dandruff shampoo to reduce dandruff, itching, scalp histamine, and scalp microbiome
5. I have been given the right to refuse to provide information if I object to it
6. I was also given the right to withdraw as a participant in this study at any time without any consequences
7. I understand and I have been informed that all information I will provide will be fully used for study purposes
8. I have also been given information that my personal identity will be guaranteed to be kept confidential, both in reports and in the publication of study results
9. I consent to the use of all anonymous data and samples collected from me during this study for use, either individually or pooled with other participants, in analyzes of this study, in print publications, or for other purposes as determined by the investigator

Date: _____

Study Participant	Investigator
(_____)	(_____)

*For participant

CONSENT FORM TO PARTICIPATE IN THE STUDY (INFORMED CONSENT)**

10. I : _____ Age : ____ years
    Address : _____
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    Declare willingness to participate in this study with the title: The ability of anti-dandruff shampoo to reduce dandruff, itching, scalp histamine, and scalp microbiome in subjects with moderate to severe dandruff
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17. I have also been given information that my personal identity will be guaranteed to be kept confidential, both in reports and in the publication of study results
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Date: _____

Study Participant	Investigator
(_____)	(_____)

**For investigator