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A pilot study to understand the influence of different head washing methods for anti-dandruff

Submission date
24/02/2021

Recruitment status
No longer recruiting

Registration date
03/03/2021

Overall study status
Completed

Last Edited
19/05/2023

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Dandruff is a common scalp condition that can be improved by regular use of shampoos containing anti-fungal actives. The efficacy of anti-dandruff shampoos can be assessed by measuring scalp flaking, one of the important dandruff symptoms.
The aim of the study was to test different head washing techniques for the effect on dandruff reduction.

Who can participate?
Adults aged 18 - 60 years, with dandruff.

What does the study involve?
Participants were divided into 2 groups using an on-site controlled washing method or salon-staff washing method. Both groups employed hair washing at a frequency of three-times a week, and dandruff measurement occured once a week from the baseline assessment.

What are the possible benefits and risks of participating?
None

Where is the study run from?
Dahua Garden Hair Salon (China)

When is the study starting and how long is it expected to run for?
March 2016 to January 2017

Who is funding the study?
Unilever (UK/China)

Who is the main contact?
Yuanpei Li, yuanpeili.research@gmail.com

Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
HAI-DDF-2517

Study information

Scientific Title
Comparison of whole-head and split-head design for the clinical evaluation of anti-dandruff shampoo efficacy

Study objectives
There is a response difference in anti-dandruff efficacy between the on-site controlling method and the salon-staff wash method

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 03/03/2016, Shanghai Nutrition Society (A18, No 380, Fenglin Rd., Shanghai, 200231, China; +86-33676001; yyxh@shhyy.com), ref: 2016-33-01

Study design
Single-center double-blind interventional randomized controlled trial

Primary study design
Interventional

Study type(s)

Other

Health condition(s) or problem(s) studied
Decrease dandruff and improve scalp health

Interventions
This is a single-center, double-blind, randomized, mix genders study. Subjects will remain in the study for about 7 weeks, including a 2-week run-in phase, 1-week balancing, and a 4-week test phase. There will be 2 cells included in this study: one is to follow the whole-head wash procedure with the on-site controlling method, the other is to follow the half-head wash procedure with the routine salon-staff wash method.

All qualifying dandruff subjects will be randomly allocated (by sealed envelope) into either of the two wash regime cells:
Cell 1: Whole-head, on-site controlling wash, subjects will be randomly allocated to use either test shampoo by themselves at the study site with specific instructions under supervision.
Cell 2: Half-head, salon-staff wash, both two test shampoo will be used on either side of their head randomly by salon staff.

During the test phase, there will be 12 product application visits (three per week) and 5 dandruff assessments including baseline, week 1 to week 4 (once per week).

Intervention Type
Supplement

Primary outcome(s)
Scalp visual assessment by a trained assessor at baseline, and once per week from week 1- week 4.

Key secondary outcome(s))
Adverse events will be measured and recorded throughout the study (4 weeks)

Completion date
19/01/2017

Eligibility

Key inclusion criteria
1. External subjects (not employees from Unilever or S.P.R.I.M. or Recruiting agency)
2. Aged between 18 and 60 years (inclusive)
3. Dandruff scalp condition (both sides half head total weighted head score AF equivalent ≥32 with grade C, difference between two sides <12) at screen v1 and rescreen v2
4. Subject’s scalp is free from cuts and abrasions
5. Understand the test procedure and agree to adhere to study requirements
6. Hair wash frequency ≥twice per week

Participant type(s)
Healthy volunteer

Healthy volunteers allowed

No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
120

Key exclusion criteria
1. Currently pregnant, trying to be pregnant or breastfeeding (female only)
2. Have a history of serious illness that may require regular systemic medication (e.g. cancer, thyroid dysfunction, liver dysfunction) which may influence the study outcome (at the discretion of the Study Doctor). Subjects with stable thyroid conditions (medication / dosage has not changed within 12 months of the start of the study) may be included at the discretion of the Study Doctor
3. Current or frequent systemic treatment by a doctor for any active skin condition, on any body site
4. Sufferers of eczema of any area of the head or neck (during adult life)
5. Seborrhoeic dermatitis on the head or neck or severe dandruff, currently or within last 6 months
6. Diagnosed with psoriasis and have active lesions within last 2 years
7. Use of systemic anti-inflammatory medication on a frequent basis (at the discretion of the Study Doctor) Use of topical steroids on the scalp currently or within last 6 months
8. Recent or current regular use of systemic or inhaled steroids
9. Regular use of any other medication / topical products which might affect the outcome of the study (at the discretion of the Study Doctor)
10. Hair dyed/permed or chemically treated within 2 weeks of the run-in period
11. Have head lice or ringworm at any point in the study • Have any known allergies or sensitivities to ingredients in study products
12. Hair loss greater than Hamilton grade 3 for male or Ludwig grade 1 for female
13. Use of ketoconazole-based shampoo (e.g. Nizoral, Neutrogena Long-lasting) within last 6 months or Selenium sulfide-based shampoo (e.g. Selsun, L'Oreal Intensive Anti-Dandruff, Head and Shoulders intensive) within the last 3 months
14. Use of anti-dandruff shampoo or other anti-dandruff hair/scalp care products within the last 2 months
15. Concurrent participation in another scalp clinical study
16. Use of any medicine which in the opinion of the Study Doctor may affect the outcome of the study

Date of first enrolment
28/10/2016

Date of final enrolment
30/12/2016

Locations

Countries of recruitment
China

Study participating centre
Dahua Garden Hair Salon
No.151 Jiandong Road
Beilin District
Xi'an City
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710000

Sponsor information

Organisation
Unilever (China)

ROR
https://ror.org/01b0cs606

Funder(s)

Funder type
Industry

Funder Name
Unilever

Alternative Name(s)
Unilever Global, Unilever PLC, U

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		31/05/2021	19/05/2023	Yes	No