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The effectiveness and safety evaluation of hair growth promotor containing teak leaf extract

Submission date
04/12/2023

Recruitment status
No longer recruiting

Registration date
08/01/2024

Overall study status
Completed

Last Edited
30/10/2024

Condition category
Skin and Connective Tissue Diseases

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

Plain English summary of protocol
Background and aims
Teak leaf extract exhibits 5-alpha reductase inhibitory activity and other biological activities related to hair growth applications. Therefore, teak leaf extract is a good source of natural ingredients for developing hair growth promotors. This study aims to evaluate the effectiveness and safety of hair tonic containing teak leaf extract

Who can participate?
Men who suffer from androgenic alopecia (type II-V), aged 20-60 years old

What does the study involve?
This is a study to evaluate of effectiveness and safety of a hair tonic containing teak leaf extract compared with 5% minoxidil (positive control) and a placebo.

What are the possible benefits and risks of participating?
The participants who enroll in this study might benefit from the treatment of hair growth with less of side effects. However, the participants might have skin irritation to the received product which can be treated by a dermatologist until complete recovery.

Where is the study run from?
The Cosmetics and Natural Products Research Center, Naresuan University (Thailand)

When is the study starting and how long is it expected to run for?
July 2021 to February 2022

Who is funding the study?
The National Research Council of Thailand (NRCT) (Grant number N21A640421) (Thailand)

Who is the main contact?
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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 effectiveness and safety evaluation of hair growth promotor containing Tectona grandis L. (Teak) leaves extract

Study objectives
Hair tonic containing teak leaf extract could promote hair growth effects

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 20/07/2021, Naresuan University Institutional Review Board (NU-IRB) (4th Floor Mahathammaracha Building, Division of Research Promotion, Naresuan University, Phitsanulok, 65000, Thailand; +6655968752; nu-irb-board1@nu.ac.th), ref: P10123/64

Study design
Double-blind randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

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

Study type(s)
Safety, Efficacy

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied
Hair growth promotor in men who suffer from androgenic alopecia

Interventions
The participants were randomized into 3 groups:
1. Patients receiving a 5% minoxidil (positive control),
2. Patients receiving a hair tonic containing teak leaf extract (the tested product)
3. Patients receiving a base of hair tonic without teak leaf extract (placebo)

The participants were identified by a Unicode which was blinded to investigators. All products were uniformly packaged and labeled with codes by a researcher not involved in the investigation. The participants were assigned to apply 3-5 drops (0.5 mL) of the received product twice a day (morning and night) and to use the provided shampoo for washing their hair at least once a day. Participants were not permitted to use other hair growth promoters.

Intervention Type
Supplement

Primary outcome measure
1. Target area hair count (TAHC), hair density, anagen hair count, and telogen hair count were measured by macro-photography trichoscopy Leviacam at baseline and every 4 weeks for a total duration of 24 weeks
2. Hair shedding measured using a combing test macro-photography trichoscopy Levicam at baseline and every 4 weeks for a total duration of 24 weeks
3. Safety and adverse effects measured by a dermatologist evaluation at baseline and every 4 weeks for a total duration of 24 weeks
4. Hair growth satisfaction measured using a questionnaire at the end of the study (week 24)

Secondary outcome measures
There were no secondary outcome measures

Overall study start date
10/01/2021

Completion date
20/07/2022

Eligibility

Key inclusion criteria
Men who suffered from androgenic alopecia defined by Hamilton-Norwood type II to V, age 20-60 years old.

Participant type(s)
Patient

Age group
Adult

Lower age limit
20 Years

Upper age limit
60 Years

Sex
Male

Target number of participants
90

Total final enrolment
90

Key exclusion criteria
1. A lesion on the scalp
2. Sensitivity to hair growth promotors or minoxidil
3. Use of other hair-regrowth products for 3 months and/or minoxidil for 6 months before enrolling in this project
4. Systemic steroids for more than 14 days within 2 months before baseline evaluation
5. Medical history of radiation on the scalp
6. Personal chronic decreases i.e. chronic kidney disease, and non-controlled blood pressure

Date of first enrolment
01/08/2021

Date of final enrolment
20/02/2022

Locations

Countries of recruitment
Thailand

Study participating centre
The Cosmetics and Natural Products Research Center
Naresuan University, 99 Moo 9, Tha Pho Subdistrict, Mueang District
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Sponsor information

Organisation
National Research Council of Thailand

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Sponsor type
Government

Website
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ROR
https://ror.org/018wfhg78

Funder(s)

Funder type
Government

Funder Name
National Research Council of Thailand

Alternative Name(s)
NRCT

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Thailand

Results and Publications

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

Intention to publish date
01/02/2024

Individual participant data (IPD) sharing plan
The datasets generated during the study were stored in a non-publicly available repository at the Faculty of Pharmaceutical Sciences, Narasuan University, Thailand.

IPD sharing plan summary
Stored in non-publicly available repository, Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			02/01/2024	No	No
Results article		30/10/2024	30/10/2024	Yes	No