

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

Submission date 04/12/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 08/01/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 30/10/2024	Condition category Skin and Connective Tissue Diseases	<input type="checkbox"/> 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 promoters. 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 promoters 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 diseases 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

Sponsor details

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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