

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

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<b>Registration date</b> 08/01/2024	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 30/10/2024	<b>Condition category</b> Skin and Connective Tissue Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<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 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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# Contact information

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Public, Scientific, Principal investigator

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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 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

### Study type(s)

Safety, Efficacy

### 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(s)**

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)

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

There were no secondary outcome measures

### **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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

20 years

### **Upper age limit**

60 years

**Sex**

Male

**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  
Phitsanilok  
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65000

**Sponsor information****Organisation**

National Research Council of Thailand

**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

### 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?
<a href="#">Results article</a>		30/10/2024	30/10/2024	Yes	No
<a href="#">Protocol file</a>			02/01/2024	No	No