

A multi-centre, double-blind, randomised, vehicle-controlled study for a quantitative estimation of hair re-growth in male subjects with androgenetic alopecia treated over 6 month with two ethanolic PSK 3841 solutions (2.5% and 5%)

Submission date 12/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 06/10/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 19/02/2014	Condition category Skin and Connective Tissue Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

PSK 3841/2001

Study information

Scientific Title

Study objectives

The hypotheses underlying this study were:

1. Once-daily treatment with PSK 3841 solution at 5% was to result in a significant increase in hair growth, when compared to daily treatment with vehicle
2. There should be a difference between the two active treatments (2.5% and 5% once-a-day)
3. Treatments should be safe and well tolerated in men with male pattern baldness

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Androgenetic alopecia.

Interventions

PSK 3841 solutions (2.5% or 5%).

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

PSK 3841

Primary outcome measure

1. Total and anagen hair numbers
2. Safety and tolerability

Secondary outcome measures

1. Investigator hair scalp assessment and patient hair growth questionnaire
2. Pharmacokinetics of PSK 3841 and its metabolites

Overall study start date

20/10/2002

Completion date

04/08/2003

Eligibility**Key inclusion criteria**

1. Men aged between 18 and 50 years with an androgenetic alopecia rated as Norwood-Hamilton stage IIIa, IIIv, IV, IVa and V
2. Subjects in good health, with no relevant abnormalities in their medical history, physical examination and vital signs
3. Willingness to refrain from using any hair enhancement products or procedures for the duration of the study

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Male

Target number of participants

120

Key exclusion criteria

1. Men whose female partner is pregnant or of childbearing potential and not using adequate efficacious contraception
2. Subjects with hair loss due to causes other than androgenetic balding
3. Subjects with scalp diseases other than androgenetic balding
4. Subjects who have had a clinically important illness within the past 6 months before the study entry, which potentially could affect hair growth/loss
5. Any pathology or abnormality of the skin in the areas to be treated

Date of first enrolment

20/10/2002

Date of final enrolment

04/08/2003

Locations

Countries of recruitment

Belgium

United Kingdom

Study participating centre

9 Rue du Sondard

Tournai

Belgium

7500

Sponsor information

Organisation

ProStrakan Pharmaceuticals (France)

Sponsor details

102 Route de Noisy

Romainville

Paris

France

932230

Sponsor type

Industry

ROR

<https://ror.org/03bvd4t69>

Funder(s)

Funder type

Industry

Funder Name

Proskelia Pharmaceuticals - a part of ProStrakan Pharmaceuticals.

Results and Publications**Publication and dissemination plan**

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration