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%)

Recruitment status	Prospectively registered
No longer recruiting	Protocol
Overall study status	Statistical analysis plan
Completed	Results
Condition category	Individual participant data
5 5	Record updated in last year
	No longer recruiting Overall study status

Plain English summary of protocolNot provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Dominique Van Heste

Contact details

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Additional identifiers

Protocol serial number 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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Male

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

United Kingdom

Belgium

Study participating centre

9 Rue du Sondard

Tournai Belgium 7500

Sponsor information

Organisation

ProStrakan Pharmaceuticals (France)

ROR

https://ror.org/03bvd4t69

Funder(s)

Funder type

Industry

Funder Name

Proskelia Pharmaceuticals - a part of ProStrakan Pharmaceuticals.

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration