

A double blind, randomised, vehicle-controlled, safety and tolerance study of topical PSK 3841 solution at 5% administered twice daily over four weeks to healthy Caucasian males with androgenetic alopecia

Submission date 12/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 06/10/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 14/02/2008	Condition category Skin and Connective Tissue Diseases	<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

Contact name

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Contact details

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France
35000

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Study objectives

To assess the systemic and local safety and tolerance of 5% PSK 3841 solution versus vehicle (70% ethanol) when administered topically twice-a-day over 4 weeks on the scalp of Caucasian males with androgenic alopecia.

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

5% PSK 3841 solution or vehicle.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

PSK 3841

Primary outcome measure

Safety and tolerability based on pharmacodynamic endocrine profile (gonadotropins, steroids) on day 1, 15 and 28 of treatment.

Secondary outcome measures

1. To characterize the pharmacokinetics of PSK 3841 and its metabolites in alopecic males treated twice daily with topical applications on the scalp over a 4-week period
2. To assess whether an eventual exposure to PSK 3841 in untreated female partners occurred under real life conditions during the study

Overall study start date

13/06/2002

Completion date

20/09/2002

Eligibility**Key inclusion criteria**

For male subjects:

1. Caucasian healthy male subjects aged between 18 and 50 years old with an androgenic alopecia graded as IIIa, IIIv, IV, IVa or V according to Norwood-Hamilton classification
2. Subjects cohabiting with their female partner during all the study treatment

For their female partners:

1. Healthy female subjects

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

A total of 30 couples (30 treated males, 30 untreated females).

Key exclusion criteria

For male subjects:

1. Mobile working activities preventing sleeping at home on a regular basis
2. Baldness due to medical illness, alopecia aerata, trichotillomania or any other form of pathologic alopecia other than androgenetic alopecia
3. Any pathology or abnormality of the skin in the areas to be treated
4. History of skin allergy
5. Regular use of medication which might interfere with the results of the study

For their female partners:

1. Mobile working activities preventing sleeping at home on a regular basis
2. Pregnant or lactating female
3. Female of childbearing potential without adequate efficacious contraception

Date of first enrolment

13/06/2002

Date of final enrolment

20/09/2002

Locations

Countries of recruitment

France

Study participating centre

7-9 Rue Jean Louis Bertrand

Rennes

France

35000

Sponsor information

Organisation

ProStrakan Pharmaceuticals (France)

Sponsor details

102 Route de Noisy

Romainville

Paris

France

93230

Sponsor type

Industry

Website

<http://www.prostrakan.com>

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