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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	Recruitment status	[_] Prospectively registered
12/09/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
06/10/2005	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
14/02/2008	Skin and Connective Tissue Diseases	[_] 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 3841/1011

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