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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

Registration date
06/10/2005

Last Edited
19/02/2014

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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