

# 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

**Registration date**  
06/10/2005

**Last Edited**  
14/02/2008

**Recruitment status**  
No longer recruiting

**Overall study status**  
Completed

**Condition category**  
Skin and Connective  
Tissue Diseases



Retrospectively registered



Protocol not yet added



SAP not yet added



Results not yet added and study completed for more than 2 years



Raw data not yet added



Study completed

## Plain English Summary

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr Evelyne Guénolé

### Contact details

7-9 Rue Jean Louis Bertrand  
Rennes  
France  
35000

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

**Protocol/serial number**

PSK 3841/1011

## **Study information**

**Scientific Title**

**Study hypothesis**

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**

**Condition**

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

### **Overall study end date**

20/09/2002

## **Eligibility**

### **Participant 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).

### **Participant 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

**Recruitment start date**

13/06/2002

**Recruitment end date**

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