

# Pharmacokinetics of two different formulations of finasteride (topical and oral) in male volunteers with androgeneic alopecia

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 08/08/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 08/08/2013	<b>Condition category</b> Skin and Connective Tissue Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Androgenetic alopecia (hair loss) in men is caused by a progressive decrease in the density of terminal hairs (thick dark hair) and a concurrent increase in the density of short, non-pigmented hairs. This effect is attributed to the shrinking of the hair follicle, which is associated with a substantial reduction in hair diameter. Although the mechanism of these changes has not been definitively established, male pattern baldness is known to depend on the hormones, in particular, on the androgen dihydrotestosterone (DHT), which is produced from testosterone. In fact, in the scalp of men with androgenetic alopecia an increased rate of conversion of testosterone into DHT has been detected.

Polichem has developed a new topical formulation of finasteride 0.25% (P-3074) that maintains a balanced amount of finasteride at the surface of the scalp for enough time to allow the active compound to penetrate through the skin layers, down to the layer of the skin where most of the hair bulbs are located. The aim of the present study is to compare the pharmacokinetic (PK) profile (action of the drug in the body) of finasteride after single and multiple dose administration of finasteride topical solution (applied onto the scalp) compared with a finasteride oral tablet.

### Who can take participate?

Twenty-four male volunteers aged between 18-65 years with recession of the frontal hairline and hair loss in the vertex or crown, or loss of hair over the frontal and vertex scalp regions were enrolled.

### What does the study involve?

Twenty-four men volunteers were randomly allocated to one of the two groups: 12 subjects received finasteride 0.25% topical solution twice a day and 12 subjects received finasteride 1 mg oral formulation once a day. Both groups were treated for 7 days.

### What are the possible benefits and risks of participating?

Since this was a phase I study no real potential benefits were foreseen to the volunteers participating in this study.

Potential risks of multiple dose oral administrations or topical applications of finasteride were expected to be limited to known drug-related adverse experiences of the substance mainly linked to sexual impairment: decrease of libido, reported in  $\geq 1\%$  of men treated with finasteride 1 mg, erectile dysfunction and decreased volume of ejaculate.

Other adverse reactions reported during clinical trials and/or post-marketing are the following: hypersensitivity reactions, including rash, pruritus (itching), urticaria (hives) and swelling of the lips and face; palpitation; increased hepatic enzymes; breast tenderness and enlargement; testicular pain, infertility. Breast cancer has been reported in men taking finasteride 5 mg during the post-marketing period in the UK but there have been no reported cases of male breast cancer associated with 1 mg finasteride use.

Where is the study run from?

The study was conducted in the CROSS Research Phase I Unit located in Arzo, Switzerland.

When is the study starting and how long is it expected to run for?

The patients were treated between August 2011 and September 2011.

Where does the study take place?

The study was conducted in the CROSS Research Phase I Unit located in Arzo, Switzerland.

Who is funding the study?

Polichem SA, Switzerland.

Who is the main contact?

Dr Renata Palmieri

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## Contact information

**Type(s)**

Scientific

**Contact name**

Dr Milko Radicioni

**Contact details**

CROSS Research S.A.

Phase I Unit - Via F.A. Giorgioli 14

Arzo

Switzerland

6864

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

## Study information

### Scientific Title

Pharmacokinetics of topical (0.25% solution bid) and oral (1 mg od) finasteride after single and 7 days multiple dose in male volunteers with androgeneic alopecia

### Study objectives

To compare the pharmacokinetic profiles of finasteride in male volunteers with androgeneic alopecia after single and multiple dose administration of finasteride 0.25% solution vs. finasteride 1 mg oral formulation.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Approved by Cantonal Ethics Committee (Comitato Etico Cantonale), Canton Ticino, Switzerland, on 22nd March 2011, Ref. CE2421.

### Study design

Single centre randomised open-label parallel group study

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Other

### Study type(s)

Treatment

### Participant information sheet

Not available in web format, please contact Renata Palmieri: [renata.palmieri@polichem.com](mailto:renata.palmieri@polichem.com) to request a patient information sheet

### Health condition(s) or problem(s) studied

Androgeneic alopecia

### Interventions

1. First group: 7-day treatment of the scalp skin area with a new topical finasteride formulation (0.25%) b.i.d. (every 12 hours)
2. Second group: 7-day treatment with finasteride oral formulation 1 mg o.d.

### Intervention Type

Drug

**Phase**

Not Specified

**Drug/device/biological/vaccine name(s)**

Finasteride

**Primary outcome measure**

Plasma levels of finasteride after single and multiple dose administration of topical or oral finasteride formulation measured using a validated UPLC-MS/MS method.

Time points:

1. Before the first drug administration
2. 0.5, 1, 2, 3, 4, 5, 6, 8, 10, 12, 16, 20, 24 h after the first dose
3. Before last drug administration
4. 0.5, 1, 2, 3, 4, 5, 6, 8, 10, 12, 24 and 36 h after the last dose.

**Secondary outcome measures**

1. Plasma levels of testosterone and dihydrotestosterone after single and multiple dose administration of topical or oral finasteride formulation determined using a validated LC-MS/MS method.

Time points:

1. Before the first drug administration
2. 6, 12 and 24 h after the first dose
3. Before last drug administration
4. 6, 12, 24 and 36 h after the last dose

2. Adverse events (AEs), vital signs (BP, HR), ECG, physical examination, laboratory parameters measured at screening visit and at the end of the trial (final visit).

**Overall study start date**

22/08/2011

**Completion date**

06/09/2011

**Eligibility****Key inclusion criteria**

1. Sex: male
2. Age: 18-65 year-old inclusive
3. Androgenic alopecia: recession of the frontal hairline and hair loss in the vertex or crown or loss of hair over the frontal and vertex scalp regions, corresponding to at least stage 2 of the Hamilton-Norwood scale
4. Body Mass Index (BMI):  $18 < \text{BMI} < 30 \text{ kg/m}^2$ ;
5. Vital signs: Systolic Blood Pressure (SBP) 100-139 mmHg, Diastolic Blood Pressure (DBP) 50-89 mmHg, Heart Rate (HR) 50-90 bpm, measured after 5 min of rest in the sitting position
6. Full comprehension: ability to comprehend the full nature and purpose of the study, including possible risks and side effects; ability to co-operate with the investigator and to comply with the requirements of the entire study
7. Informed Consent: signed written informed consent prior to inclusion in the study

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

65 Years

**Sex**

Male

**Target number of participants**

24

**Key exclusion criteria**

1. Electrocardiogram (ECG) (12-leads) (supine position): clinically relevant abnormalities
2. Physical findings: clinically relevant abnormal physical findings which could interfere with the objectives of the study; in particular, skin damage such as abrasion, hyperkeratosis or any abnormal findings in the scalp
3. Laboratory analyses: clinically relevant abnormal laboratory values indicative of physical illness
4. Allergy: ascertained or presumptive hypersensitivity to the active principle and/or formulations' ingredients; history of anaphylaxis to drugs or allergic reactions in general, which the Investigator considers may affect the outcome of the study
5. Diseases: relevant history of renal, hepatic, gastrointestinal, cardiovascular, respiratory, skin, haematological, endocrine or neurological diseases, that may interfere with the aim of the study
6. Medications: medications, including over the counter (OTC) drugs, for 2 weeks before the start of the study
7. Investigative drug trials: participation in the evaluation of any drug for 3 months before this study, calculated from the first day of the month following the last visit of the previous study
8. Blood donation: blood donations for 3 months before this study
9. Drug, alcohol, caffeine, tobacco: history of drug, alcohol [ $>2$  drinks/day], caffeine ( $>5$  cups coffee/tea/day) or tobacco abuse ( $>10$  cigarettes/day)
10. Abnormal diets ( $<1600$  or  $>3500$  kcal/day) or substantial changes in eating habits in the 4 weeks before this study

**Date of first enrolment**

22/08/2011

**Date of final enrolment**

06/09/2011

**Locations**

**Countries of recruitment**

Switzerland

**Study participating centre**  
**CROSS Research S.A.**  
Arzo  
Switzerland  
6864

## **Sponsor information**

**Organisation**  
Polichem S.A. (Switzerland)

**Sponsor details**  
Via Senago 42D  
Lugano  
Switzerland  
6912

**Sponsor type**  
Industry

**ROR**  
<https://ror.org/05735qy63>

## **Funder(s)**

**Funder type**  
Industry

**Funder Name**  
Polichem S.A. (Switzerland)

## **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