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

Submission date
30/07/2013

Recruitment status
No longer recruiting

Registration date
08/08/2013

Overall study status
Completed

Last Edited
08/08/2013

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

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 ≥ 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

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Additional identifiers

Protocol serial number
PM1024

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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))

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).

Completion date
06/09/2011

Eligibility

Key inclusion criteria
1. Sex: male
2. Age: 18-65 year-old inclusive
3. Androgeneic 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 < BMI < 30 kg/m2;
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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
Male

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)

ROR
https://ror.org/05735qy63

Funder(s)

Funder type
Industry

Funder Name
Polichem S.A. (Switzerland)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration