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Study of two different formulations of finasteride in male volunteers with androgenetic alopecia

Submission date
30/07/2012

Recruitment status
No longer recruiting

Registration date
08/08/2012

Overall study status
Completed

Last Edited
13/09/2016

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, also known as male-pattern baldness, is a common form of hair loss. It is known to depend on male sex hormones (androgens), in particular on dihydrotestosterone (DHT), which causes the hair follicles to shrink. The drug finasteride works by preventing testosterone from being converted to DHT, allowing the hair follicles to regain their normal size. Polichem has developed a new topical formulation of finasteride that maintains a balanced amount of finasteride at the surface of the scalp for enough time to allow it to go through the skin layers to where most of the hair bulbs are located. The aim of this study is to investigate the effects of finasteride on testosterone and DHT levels in the scalp and in the blood of men with androgenetic alopecia.

Who can participate?
Male volunteers aged 18-65 with androgenetic alopecia

What does the study involve?
Participants are randomly allocated to one of three groups. All groups of volunteers are treated for 7 days. The first group are treated with finasteride topical solution twice a day, the second group are treated with finasteride topical solution once a day, and the third group are treated with finasteride oral formulation once a day. Two weeks before starting the treatment and after the last dose two scalp samples (biopsies) are taken in order to assess testosterone and DHT levels. Blood samples are collected before the first treatment, before the last dose, and 6 and 12 hours after the last dose, in order to measure blood levels of testosterone and DHT.

What are the possible benefits and risks of participating?
No benefits are expected for the volunteers participating in this study. Known side effects of finasteride include sexual impairment (decreased libido, erectile dysfunction, decreased volume of ejaculate). Other possible side effects include: rash, pruritus (severe itching), urticaria (hives), swelling of the lips and face, palpitation (irregular heartbeat), breast tenderness and

enlargement, testicular pain, and infertility. Breast cancer has been reported in men taking a higher dose of finasteride but there have been no reported cases of male breast cancer associated with the dose used in this study.

Where is the study run from?
The CROSS Research Phase I Unit (Switzerland)

When is the study starting and how long is it expected to run for?
August to September 2012

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
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6864

Additional identifiers

Protocol serial number
PM1227

Study information

Scientific Title
Prospective, comparative, pharmacodynamic study of two topical dosage regimens of a new finasteride formulation (0.25% o.d. and b.i.d.) and oral finasteride (1 mg o.d.) after 7 days multiple dose administration in male volunteers with androgenetic alopecia

Study objectives
To assess the pharmacodynamic profile of a topical formulation of finasteride 0.25% o.d. and b.i.d. and of oral finasteride (1mg o.d.) in terms of testosterone and dihydrotestosterone concentrations in the scalp and in serum.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Comitato Etico Cantonale, Canton Ticino, Switzerland, 03/04/2012, ref: EC2548

Study design
Single=centre randomised open-label parallel=group pharmacodynamic exploratory study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Androgenetic alopecia

Interventions
First and second group: 7-day treatment of the scalp skin area with a new topical finasteride formulation (0.25%) o.d. or b.i.d. (every 12 hours), the third group of volunteers will be treated with finasteride oral formulation 1 mg o.d. Two weeks before starting the treatment and after last treatment dose, two scalp biopsies will be taken.

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome(s)
Serum and scalp concentration of testosterone and dihydrotestosterone before and after multiple dose administration of topical or oral finasteride formulation

Key secondary outcome(s))
1. Adverse events
2. Vital signs (blood pressure, heart rate)
3. Electrocardiogram
4. Physical examination
5. Laboratory parameters

Completion date
07/09/2012

Eligibility

Key inclusion criteria

1. Sex - male
2. Age: 18-65 year olds inclusive
3. Androgenetic 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. BMI: 18, TBMI, T30 kg/m2
5. Vital signs: SBP 100-139 mmHg, DBP 50-89 mmHg, HR 50-90 bpm, measured after 5 min of rest in the sitting position
6. Full comprehension:
6.1. Ability to comprehend the full nature and purpose of the study, including possible risks and side effects
6.2. 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. 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
03/08/2012

Date of final enrolment
07/09/2012

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes