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A study in healthy male and female volunteers to assess how different formulations of the test medicine (VDPHL01) are taken up by the body

Submission date
14/07/2023

Recruitment status
No longer recruiting

Registration date
19/07/2023

Overall study status
Completed

Last Edited
13/08/2026

Condition category
Skin and Connective Tissue Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
The Sponsor is developing the test medicine, VDPHL01, for the potential treatment of Androgenetic Alopecia (AGA), also known as male or female pattern hair loss. AGA is the most common type of hair loss, affecting up to 50% of males and females. This type of hair loss is related to both a genetically predetermined excessive response of the hair follicles to hormones called androgens, as well as higher levels of these hormones, which lead to a shorter life cycle of hair growth and the growth of shorter and thinner strands of hair.
This study in healthy volunteers aims to answer this question:
*How do blood levels of the test medicine compare when it's given as different formulations, and compare to an already approved and marketed reference product?
This study will also provide more information on the safety and tolerability of the test medicine, and any side effects.

Who can participate?
Healthy male and female participants, aged 18 to 55.

What does the study involve?
Participants will take part in 6 study periods. In 5 of those study periods, they will take a single oral dose of new formulations (recipes) of the test medicine, as tablets, and in 1 period they will take a single oral dose of an approved and marketed reference product, as tablets. In Periods 1 to 5, the dose of test medicine will be taken fasted, and in Period 6 the test medicine may be taken with food. They'll stay in the clinic for 3 nights in each study period, and there will be a minimum of 7 days between each dose of study medicine. Volunteers will have a follow-up phone call about 5 days after their final dose of test medicine, and will take up to 14 weeks to finish the study.

What are the possible risks and benefits of participating?
1. As this is a Phase I study, the most relevant population is healthy volunteers. It is considered that the risk/benefit evaluation in this study supports the use of healthy volunteers.
2. This study will involve women of childbearing potential. However, as minoxidil has shown

reproductive toxicity, women will only be allowed to participate if they are using highly effective contraception which is outlined to the volunteers in the Participant Information Sheet and Informed Consent Form (PIS/ICF).
3. There is always a risk that the stipend in healthy volunteer studies could represent coercion. The time spent in the clinic, travel, inconvenience and other expenses factor in calculating the stipend. Perception of risk is not considered in this calculation.
4. When investigating new medicines, there is always a risk of unexpected side effects and occasionally allergic reactions. Volunteers will be closely monitored during the study.
5. Volunteers may experience side effects from the test medicine and/or reference product in this study. Full information on possible side effects is provided to volunteers in the PIS/ICF.
6. There will be an extended period of fasting for the volunteers taking part in this study. To ensure an adequate fluid intake, the volunteers will be allowed ad libitum fluids and will be monitored for signs of dehydration and fatigue.
7. Blood samples will be collected during the study. Collection of these samples can cause soreness and bruising of the arms, but these problems usually clear up within a few days to a few weeks.
8. ECG stickers on volunteers' chests and limbs may cause some local irritation and may be uncomfortable to remove, but volunteers will be closely monitored to ensure any local irritation does not persist.

Where is the study run from?
Veradermics Inc. (USA)

When is the study starting and how long is it expected to run for?
October 2023 until February 2024

Who is funding the study?
Veradermics Inc. (USA)

Who is the main contact?
recruitment@weneedyou.co.uk

Contact information

Type(s)
Principal investigator, Public, Scientific

Contact name
Dr Phil Evans

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Additional identifiers

Integrated Research Application System (IRAS)
1007785

Study information

Scientific Title
A phase 1, single-part, non-randomised, open-label, six-period sequential crossover study designed to evaluate the pharmacokinetic profile of VDPHL01 following single dose administration of novel VDPHL01 modified release formulations in comparison to a reference minoxidil immediate release formulation in healthy subjects

Study objectives
The trial will meet the following primary and secondary objectives:
Primary:
To evaluate the PK profile and determine the relative bioavailability of VDPHL01 following single oral dosing of VDPHL01 MR prototype tablets vs a reference immediate-release (IR) formulation in healthy subjects in the fasted state

Secondary:
To provide additional information on the safety and tolerability of single oral doses of VDPHL01 MR prototype tablet formulations and a reference IR formulation in healthy subjects

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 27/09/2023, London Surrey Borders REC (2nd Floor 2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8057; Surreyborders.rec@hra.nhs.uk), ref: 23/LO/0521

Primary study design
Interventional

Allocation
Non-randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Crossover

Purpose
Phase 1 study in healthy volunteers

Study type(s)
Other

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

Interventions
This is a non-randomised, open-label study. Healthy volunteers will receive single oral doses of up to 10 mg of a new tablet formulation of the test medicine in up to 5 study periods, and a single 2.5 mg oral dose of an approved and marketed reference product in one study period. Volunteers will be dosed in the fasted state in Periods 1 to 5, and they will be dosed in the fasted or fed state in Period 6 depending on the data from the previous study periods. There will be a minimum 7-day break between each dosing occasion. Volunteers will be discharged on Day 3 in each study period.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
VDPHL01 Modified Release Tablet Prototype X, Loniten Tablets 2.5 mg [minoxidil]

Primary outcome(s)
1. Pharmacokinetic parameters including but not limited to Tlag, Tmax, Cmax, AUC(0-last), AUC (0-inf), and T1/2, and Frels (MR vs IR) based on PK parameters Cmax, AUC(0-last) and AUC(0-inf), where possible and appropriate, for minoxidil measured using plasma drug concentration assays at pre-dose, 0.25 h, 0.5 h, 0.75 h, 1 h, 1.5 h, 2 h, 3 h, 4 h, 6 h, 8 h, 10 h, 12 h, 18 h, 24 h, 30 h, 36 h and 48 h post-dose in each study period

Key secondary outcome(s)
1. Safety parameters measured using data on the incidence, severity and causality of AEs from screening until 48 hours post-dose in each study period, collated at the end of the study

2. Safety parameters measured using vital signs, electrocardiograms (ECGs), physical examinations and clinical laboratory safety tests, collated at pre-dose, 0.5h, 1h, 2h, 4h, 8h, 24h and 48h post-dose in each study period

Completion date
13/02/2024

Eligibility

Key inclusion criteria
1. Must provide written informed consent
2. Must be willing and able to communicate and participate in the whole study
3. Aged 18 to 55 years inclusive at the time of signing informed consent
4. Must agree to adhere to the contraception requirements defined in the Clinical Protocol
5. Males or non-pregnant, non-lactating females

6. Participants who are healthy as determined by medical evaluation including medical history, physical examination, vital signs, single 12-lead ECG, clinical laboratory profiles (haematology, clinical chemistry and urinalysis), as deemed by the investigator or designee at screening
7. Body mass index (BMI) of 18.0 to 32.0 kg/m2 as measured at screening
8. Weight ≥50 kg at screening
9. Willing to consume a high-fat breakfast, including pork

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
Yes

Age group
Adult

Lower age limit
18 Years

Upper age limit
55 Years

Sex
All

Total final enrolment
16

Key exclusion criteria
1. Serious adverse reaction or serious hypersensitivity to any drug or formulation excipients
2. Presence or history of clinically significant allergy requiring treatment, as judged by the investigator. Hay fever is allowed unless it is active
3. History of clinically significant cardiovascular, renal, hepatic, dermatological, chronic respiratory or gastrointestinal disease, neurological or psychiatric disorder, as judged by the investigator
4. Subjects with a history of cholecystectomy or gallstones
5. Subjects who do not have suitable veins for multiple venepunctures/cannulation as assessed by the investigator or delegate at screening
6. Clinically significant abnormal clinical chemistry, haematology or urinalysis as judged by the investigator. Subjects with Gilbert's Syndrome are allowed
7. Positive hepatitis B surface antigen (HBsAg), hepatitis C virus antibody (HCV Ab) or human immunodeficiency virus (HIV) 1 and 2 antibody results
8. Evidence of renal impairment at screening, as indicated by an estimated creatinine clearance (CLcr) of <80 mL/min using the Cockcroft-Gault equation
9. Evidence of orthostatic hypotension, defined as a drop in systolic blood pressure >20 mmHg upon standing, a drop in diastolic blood pressure >10 mmHg on standing or an increase in heart rate >30 bpm on standing. Or symptomatic dizziness, pre-syncope or syncope during the assessment of orthostatic hypotension
10. Any clinically significant abnormal finding on ECG at screening or pre-first dose
11. Resting supine heart rate >90 bpm
12. Resting supine systolic BP <90 mmHg

13. Resting supine diastolic BP <50 mmHg
14. Females who are pregnant or lactating (all female subjects must have a negative highly sensitive urine pregnancy test)
15. Subjects who have received any IMP in a clinical research study within the 90 days prior to Day 1 of Period 1, or less than 5 elimination half-lives prior to Day 1 of Period 1, whichever is longer
16. Donation of blood or plasma within the previous 3 months or loss of greater than 400 mL of blood
17. Subjects who are taking, or have taken, any prescribed or over-the-counter drug or herbal remedies (other than up to 4 g of paracetamol per day or HRT/hormonal contraception) in the 14 days before first IMP administration. COVID-19 vaccines are accepted concomitant medications. Exceptions may apply, as determined by the investigator, if each of the following criteria are met: medication with a short half-life if the washout is such that no PD activity is expected by the time of dosing with IMP; and if the use of medication does not jeopardise the safety of the trial subject; and if the use of medication is not considered to interfere with the objectives of the study
18. Subjects who have had a COVID-19 vaccine 3 days before first dose
19. History of any drug or alcohol abuse in the past 2 years
20. Regular alcohol consumption in males >21 units per week and in females >14 units per week (1 unit = ½ pint beer, or a 25 mL shot of 40% spirit, 1.5 to 2 units = 125 mL glass of wine, depending on type)
21. A confirmed positive alcohol breath test at screening or first admission
22. Current smokers and those who have smoked within the last 12 months
23. A confirmed positive urine cotinine test result at screening or first admission
24. Current users of e-cigarettes and nicotine replacement products and those who have used these products within the last 12 months
25. A confirmed positive drugs of abuse test result at screening or first admission
26. Male subjects with pregnant or lactating partners
27. Subjects who are, or are immediate family members of, a study site or sponsor employee
28. Failure to satisfy the investigator of fitness to participate for any other reason

Date of first enrolment
04/10/2023

Date of final enrolment
13/02/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Quotient Sciences Limited
Mere Way
Ruddington Fields
Ruddington

Nottingham
England
NG11 6JS

Sponsor information

Organisation
Veradermics Inc

Funder(s)

Funder type
Industry

Funder Name
Veradermics Inc

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available