ISRCTN97798065 https://doi.org/10.1186/ISRCTN97798065

A study of VTX958 adipate modified release tablet formulations in healthy subjects

Submission date 17/02/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 23/02/2023	**Overall study status** Completed	
Last Edited 13/05/2026	**Condition category** Other	

Plain English summary of protocol

Background and study aims
The Sponsor is developing a new formulation (recipe) of VTX958 (the test medicine) to treat inflammatory and autoimmune conditions. This healthy volunteer study will assess the performance of new formulations (recipes) of the test medicine when given as single doses and multiple doses. This study will also investigate how these recipes will be affected when taken with and without food. The extent to which the test medicine is taken up by the body will be measured and the safety and tolerability of the test medicine will be monitored throughout.

Who can participate?
Healthy male volunteers aged between 18 and 60 years.

What does the study involve?
This study will take place at one non-NHS site. In Part 1, volunteers will receive at least 3 and up to 4 single doses of the test medicine on 3 or 4 separate occasions, once daily dosing for 4 days on up to 2 possible occasions, and twice daily dosing for 4 days on 1 occasion. Volunteers will receive a follow-up phone call 5 to 7 days post final dose. Volunteers will be discharged from the study once they have completed the follow-up phone call in their final study period. Volunteers are expected to be involved in this study for approximately 15 weeks from screening to the follow-up call.

In Part 2, volunteers will receive at least 1 and up to 3 single doses of the test medicine on up to 3 separate occasions, once daily dosing for 4 days on up to 2 possible occasions, and divided doses over a 9 h period (potentially a 6 to 12 h period) on 1 possible occasion. Volunteers will receive a follow-up phone call 5 to 7 days post final dose. Volunteers will be discharged from the study once they have completed the follow-up phone call in their final study period. Volunteers are expected to be involved in this study for approximately 12 weeks from screening to the follow-up call.

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. 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.
3. 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.
4. Volunteers may experience side effects from the test medicine in this study. Full information on possible side effects is provided to volunteers in the Participant Information Sheet and Informed Consent Form.
5. 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 water up to 1 hour before dosing and will be provided with water 1 hour after dosing. Volunteers will then be allowed to drink water freely from this time. Decaffeinated fluids will be allowed freely from lunchtime on the day of dosing and will be monitored for signs of dehydration and fatigue.
6. 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.
7. 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?
Ventyx Biosciences, Inc (USA)

When is the study starting and how long is it expected to run for?
April 2023 until November 2023

Who is funding the study?
Ventyx Biosciences, Inc (USA)

Who is the main contact?
Ventyx Clinical Trial Contact, ClinicalTrials@ventyxbio.com

Contact information

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Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
1006953

Quotient Code
QSC205947

Sponsor code
VTX958-105

Study information

Scientific Title
A single and multiple dose study to evaluate the pharmacokinetics of VTX958 adipate modified release tablet formulations in healthy subjects

Study objectives
The trial will meet the following primary and secondary objectives:
Primary:
• To characterise the pharmacokinetics (PK) of VTX958 following single dose administration of VTX958 Adipate Modified Release (MR) Tablet Prototype formulations in the fasted and fed

state.
• To characterise the PK of VTX958 following single (Day 1) and multiple dose administration (Day 3) of VTX958 Adipate MR Tablet Prototype formulations in the fasted or fed state and multiple dose administration of VTX958 Adipate MR Tablet Prototype formulations in the fasted or fed state (Day 4).
• To characterise the PK of VTX958 following single (Day 1) and multiple dose administration (Day 3) of VTX958 Film Coated Tablet (Immediate Release [IR] reference) formulation in the fasted or fed state and multiple dose administration of VTX958 Film Coated Tablet (IR reference) formulation in the fasted or fed state (Day 4).
• Assess the relative bioavailability of the VTX-958 Adipate MR Tablet Prototype formulations compared to the VTX958 Film Coated Tablet (IR reference) formulation in the fasted or fed state after single (Day 1) and multiple dose administration (Day 3).
Secondary:
• To determine the relative bioavailability of the VTX958 Adipate MR Tablet Prototype formulations in the fed or fasted state after multiple dose administration relative to the fed or fasted state.
• To assess safety and tolerability for single and multiple doses of VTX958.Adipate when administered as MR Tablet Prototype formulations.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 03/04/2023, Wales REC 2 (Health and Care Research Wales, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, United Kingdom; +44 (0)2071048222, +44 (0) 2920230457, +44 (0)7920 565664; Wales.REC2@wales.nhs.uk), ref: 23/WA/0014

2. approved 03/04/2023, MHRA (10 South Colonnade, Canary Wharf, London, E14 4PU, United Kingdom; +44 (0)20 3080 6000; info@mhra.gov.uk), ref: CTA 57619/0001/001-0001

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Dose comparison

Assignment
Parallel

Purpose
Phase I pharmacokinetics study in healthy volunteers

Study type(s)
Other

Health condition(s) or problem(s) studied
Immune-mediated and inflammatory disorders with initial indications in psoriasis, psoriatic arthritis, and Crohn's disease.

Interventions
This is a randomised controlled trial in which healthy participants are assigned to one of two or more groups and remain in their assigned group for the duration of the study.

This healthy volunteer study will assess the performance of new formulations (recipes) of the test medicine when given as single doses and multiple doses. The extent to which the test medicine is taken up by the body will be measured and the safety and tolerability of the test medicine will be monitored throughout.

This study will take place at one non-NHS site, and is planned to enrol 20 male volunteers in Part 1 and 18 male volunteers in Part 2, aged between 18 and 60 years.

In Part 1, volunteers will receive at least 3 and up to 4 single oral doses of the test medicine (VTX958 Adipate MR Tablet Prototypes or VTX958 Film Coated Tablet) on 3 or 4 separate occasions, once daily oral dosing for 4 days on up to 2 possible occasions, and twice daily oral dosing for 4 days on 1 occasion. Volunteers are expected to be involved in this study for approximately 15 weeks from screening to the follow-up call.

In Part 2, volunteers will receive at least 1 and up to 3 single oral doses of the test medicine (VTX958 Adipate MR Tablet Prototypes or VTX958 Film Coated Tablet) on up to 3 separate occasions, once daily oral dosing for 4 days on up to 2 possible occasions, and divided oral doses over a 9 h period (potentially a 6 to 12 h period) on 1 possible occasion. Volunteers are expected to be involved in this study for approximately 12 weeks from screening to the follow-up call.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
VTX958 Adipate MR Tablet Prototypes 1-X 150 mg, VTX958 Adipate MR Tablet Prototypes M1-MX 150 mg – 300 mg, VTX958 Film Coated Tablet 125 mg (IR Reference), VTX958 Film Coated Tablet 50 mg (IR Tablet)

Primary outcome(s)
1. The appropriate PK parameters of VTX958 following single dose administration of VTX958 Adipate MR Tablet Prototype formulations including but not limited to Tmax, Cmax, C8, C24, AUC(0-24), AUC(0-inf), and T1/2 measured using blood samples collected at multiple post-dose timepoints from Period 1 Day 1 to Period 3 Day 3 (possibly Period 4 if single dose) in Part 1 and from Period 1 Day 1 to Period 2 Day 3 (possibly Period 3 if single dose) in Part 2

2. The appropriate PK parameters of VTX958 following single (Day 1) and multiple dose administration (Day 3 and Day 4) of VTX958.Adipate MR Tablet Prototype formulations including but not limited to Tmax, Cmax, C8, C24, AUC(0-24), and T1/2 (Day 3 and Day 4) measured using blood samples collected at multiple post-dose timepoints from Period 4 Day 1 to Period 6 Day 6 in Part 1 and from Period 3 Day 1 to Day 6 in Part 2

3. The appropriate PK parameters of VTX958 following single (Day 1) and multiple dose administration (Day 3 and Day 4) of VTX958 Film Coated Tablet (IR reference) formulation including but not limited to Tmax, Cmax, C8, C24, AUC(0-24), AUC(0-8), and T1/2 (Day 3 and Day 4), as appropriate measured using blood samples collected at multiple post-dose timepoints from Period 5 or Period 6 Day 1 to Day 6 in Part 1 and from Period 3 or Period 4 Day 1 to Day 6 in Part 2

4. Relative bioavailability (Frel) for Cmax, and AUC(0-24) of the VTX958 Adipate MR Tablet Prototype formulations compared to the VTX958 Film Coated Tablet (IR reference) formulation after single (Day 1) and multiple dose administration (Day 3) measured using blood samples collected at multiple post-dose timepoints from Period 4 Day 1 to Period 6 Day 6 in Part 1 and from Period 3 Day 1 to Period 4 Day 6 in Part 2

Key secondary outcome(s))
1. Relative bioavailability (Frel) for Cmax and AUC(0-24) of the VTX958 Adipate MR Tablet Prototype formulation in the fed or fasted state (Day 4) compared to the same formulation in the fed or fasted state after multiple dose administration (Day 3) measured using blood samples collected at multiple post-dose timepoints from Period 4 Day 1 to Period 6 Day 6 in Part 1 and from Period 3 Day 1 to Day 6 in Part 2

2. Safety and tolerability information measured using adverse events (AEs), vital sign measurements, electrocardiograms (ECGs), physical examinations and safety laboratory evaluations (haematology, clinical chemistry and urinalysis) at pre-dose and post-dose (from screening to follow-up phone call)

Completion date
17/11/2023

Eligibility

Key inclusion criteria
Current key inclusion criteria as of 07/05/2026:
1. Must provide written informed consent
2. Must be willing and able to communicate and participate in the whole study
3. Aged 18 to 60 years inclusive at the time of signing informed consent
4. Must agree to adhere to the contraception requirements
5. Healthy males
6. Body mass index (BMI) of 18.0 kg/m2 to 35.0 kg/m2 as measured at screening
7. Weight ≥50.0 kg at screening

Previous inclusion criteria:
Healthy human volunteer

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
Yes

Age group

Adult

Lower age limit
18 years

Upper age limit
60 years

Sex
Male

Total final enrolment
20

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. Presence of or history of clinically significant cardiovascular, renal, hepatic, dermatological, chronic respiratory or gastrointestinal disease, neurological or psychiatric disorder, as judged by the investigator
4. History of fits or seizures, including childhood febrile convulsions
5. Subjects with a history of cholecystectomy or gallstones
6. Subjects who do not have suitable veins for multiple venepunctures/cannulation as assessed by the investigator or delegate at screening
7. Evidence of current or history of SARS-CoV-2 infection within 2 weeks of first IMP administration
8. Clinically significant abnormal clinical chemistry, haematology or urinalysis at screening or first admission as judged by the investigator. Subjects with Gilbert's syndrome are not allowed.
9. Haemoglobin level below the lower limit of the laboratory reference range at screening or first admission
10. Positive hepatitis B surface antigen (HBsAg), hepatitis C virus antibody (HCV Ab) or human immunodeficiency virus (HIV) 1 and 2 antibody results at screening
11. History of treated, latent or active tuberculosis, including positive QuantiFERON assessed at screening
12. Active or presence of clinically significant opportunistic infection (e.g., invasive candidiasis or pneumocystis pneumonia), serious local infection (e.g., cellulitis, abscess) or systemic infection (e.g., septicaemia) within 3 months prior to screening
13. Presence or history of fever (body temperature >37.6°C) (e.g., a fever associated with a symptomatic viral or bacterial infection) within 2 weeks prior to the first dose
14. Subjects who have received any IMP in a clinical research study within the 90 days prior to Period 1, Day 1, or less than 5 elimination half-lives prior to Period 1, Day 1, whichever is longer
15. Subjects who have previously been administered IMP in this study. Subjects who have taken part in Part 1 are not permitted to take part in Part 2.
16. Donation of blood or plasma within the previous 3 months prior to screening or loss of greater than 400 mL of blood by any other means
17. Subjects who are taking, or have taken, any prescribed or over-the-counter drug or herbal remedies (other than up to 2 g of paracetamol per day) in the 14 days before first IMP administration. 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 pharmacodynamic (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 or any other vaccine 14 days before first IMP administration
19. Subjects who have any plans to travel abroad during the study
20. History of any drug or alcohol abuse in the past 2 years prior to screening
21. Regular alcohol consumption in males >21 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)
22. A confirmed positive alcohol breath test at screening or first admission
23. Current smokers and those who have smoked within the last 6 months prior to screening
24. A confirmed breath carbon monoxide reading of greater than 10 ppm at screening or first admission
25. Current users of e-cigarettes and nicotine replacement products and those who have used these products within the last 6 months prior to screening
26. Confirmed positive drugs of abuse test result
27. Male subjects with pregnant or lactating partners
28. Failure to satisfy the investigator of fitness to participate for any other reason

Date of first enrolment
05/04/2023

Date of final enrolment
15/09/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Quotient Sciences Limited
Mere Way
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Sponsor information

Organisation
Ventyx Biosciences, Inc.

Funder(s)

Funder type
Industry

Funder Name
Ventyx Biosciences, Inc.

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available