ISRCTN24120533 https://doi.org/10.1186/ISRCTN24120533

A study in healthy volunteers to look at how different formulations (recipes) of the test medicine firibastat (QGC001) are taken up and broken down by the body

Submission date
15/02/2022

Recruitment status
No longer recruiting

Registration date
25/02/2022

Overall study status
Completed

Last Edited
12/08/2022

Condition category
Other

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
This study will evaluate the safety (side effects), how the body processes the treatment (pharmacokinetics), and what the treatment does to the body (pharmacodynamic effects) of the drug QGC001 in healthy volunteers.

Who can participate?
Healthy volunteers aged 18 - 55 years

What does the study involve?
The study includes a 28 days screening period followed by a 7 days treatment period (participants will stay in the clinical research unit for the duration of the treatment). Af last visit will be conducted 48 hours after the last IP intake. In total, approximately 35 blood samples will be collected throughout the whole study for PK analysis. Additional samples can be collected for safety analysis at the same time as PK samples. The total amount of blood taken during the whole study, including the screening visit and follow-up will not exceed 550 mL in a 4-week period.

What are the possible benefits and risks of participating?
You will get no medical benefit from the test medicine, however development of a treatment for hypertension may benefit the population as a whole

Where is the study run from?
Quotient Sciences (UK)

When is the study starting and how long is it expected to run for?
October 2019 to March 2020

Who is funding the study?
Quantum Genomics (France)

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
2019-003748-55

Integrated Research Application System (IRAS)
271848

Protocol serial number
QGC001/1QG5

Study information

Scientific Title
A study in healthy subjects designed to evaluate the pharmacokinetic profile of firibastat (QGC001) and metabolites EC33 and QGC515 following multiple dose administration of QGC001 immediate release and modified release formulations

Study objectives
Evaluate the pharmacokinetic (PK) profiles of QGC001 and its metabolites, EC33 and QGC515, following multiple dose administration of QGC001 immediate release (IR) formulations and a modified release (MR) formulation in healthy subjects

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/01/2020, London - Surrey Borders REC (Health Research Authority, Skipton House, 80 London Road, London, SE1 6LH, UK; +44 (0)20 7972 2545; hra.approval@nhs.net), ref: 19/LO/1799

Primary study design
Interventional

Study design
Single centre multiple dose non-randomised open-label study

Study type(s)
Other

Health condition(s) or problem(s) studied
Phase 1 study in healthy volonteers

Interventions

Three cohorts of 10 subjects were enrolled. Each cohort received one of the regimens:
Cohort 1 - Regimen A - 500 mg (2 × 250 mg) QGC001 IR capsule BID on Days 1 to 6 and QD dosing on Day 7
Cohort 2 - Regimen C - 1000 mg (2 × 500 mg) QGC001 IR tablet QD for 7 days
Cohort 3 - Regimen B - 1000 mg (2 × 500 mg) QGC001 MR tablet QD for 7 days

For Regimen A, subjects will be dosed on the mornings and evenings (approximately 12 h apart) of Days 1 to 6 and on the morning of Day 7.
For Regimens B and C, subjects will be dosed on the mornings of Days 1 to 7.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
Firibastat (QGC001)

Primary outcome(s)
Evaluation of the PK profiles for each drug: Tmax, Cmax, AUC, T1/2 and Ctau by collection of blood samples for PK at D1 (Predose, 0.5, 1, 2, 3, 4, 6, 8, 10, 12, 16 and 20 hours), D2 to D6 (Predose), D7 (Predose, 0.5, 1, 2, 3, 4, 6, 8, 10, 12, 16, 20 hours), D8 (24 and 36 hours after last intake), D9 (48 hours after last intake)

Key secondary outcome(s)
Collection of additional safety and tolerability information
1. Physical examination: Baseline + D9 (48 hours post last dose)
2. Safety Labs: Baseline + D9
3. Urinalysis: Baseline + D9
4. Vital signs: Baseline, D1 to D7 (3 and 6 hours post dose) and D9 (48 hours post last dose)
5. ECG: Baseline, D1 (3 hours post dose) D2 to D7 (Predose) and D9 (48 hours post last dose)

Completion date
20/03/2020

Eligibility

Key inclusion criteria
1. Healthy males or healthy females of non-childbearing potential
2. Age 18 to 55 years at the time of signing informed consent
3. Body mass index of 18.0 to 32.0 kg/m² as measured at screening
4. Must be willing and able to communicate and participate in the whole study
5. Must provide written informed consent
6. Must agree to adhere to the contraception requirements

Participant type(s)
Healthy volunteer

Healthy volunteers allowed

No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
30

Key exclusion criteria
1. Subjects who have received any IMP in a clinical research study within the 90 days prior to Day 1
2. Subjects who are study site employees, or immediate family members of a study site or sponsor employee
3. Subjects who have previously been enrolled in this study (subjects who participated in study QSC118052 are allowed)
4. History of any drug or alcohol abuse in the past 2 years
5. Regular alcohol consumption in males >21 units per week and 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)
6. A confirmed positive alcohol breath test at screening or admission
7. Current smokers and those who have smoked within the last 12 months. A confirmed breath carbon monoxide reading of greater than 10 ppm at screening or admission
8. Current users of e-cigarettes and nicotine replacement products and those who have used these products within the last 12 months
9. Females of childbearing potential including those who are pregnant or lactating (all female subjects must have a negative urine pregnancy test). A woman is considered of childbearing potential unless she is permanently sterile (hysterectomy, bilateral salpingectomy, and bilateral oophorectomy) or is postmenopausal (had no menses for 12 months without an alternative medical cause and a serum follicle stimulating hormone [FSH] concentration ≥40 IU/L)
10. Subjects who do not have suitable veins for multiple venepunctures/cannulation as assessed by the investigator or delegate at screening
11. Clinically significant abnormal clinical chemistry, haematology or urinalysis as judged by the investigator
12. Subjects with BP <90/40 mmHg at screening and pre-dose
13. Subjects with Gilbert's Syndrome
14. Confirmed positive drugs of abuse test result
15. Positive hepatitis B surface antigen (HBsAg), hepatitis C virus antibody (HCV Ab) or human immunodeficiency virus (HIV) results
16. History of clinically significant cardiovascular, renal, hepatic, chronic respiratory or gastrointestinal disease, neurological or psychiatric disorder, as judged by the investigator
17. Serious adverse reaction or serious hypersensitivity to any drug or the formulation excipients
18. Presence or history of clinically significant allergy requiring treatment, as judged by the investigator. Hay fever is allowed unless it is active
19. Donation or loss of greater than 400 mL of blood within the previous 3 months
20. Subjects who are taking, or have taken, any prescribed or over-the-counter drugs or herbal

remedies (other than 4 g of paracetamol per day and HRT) in the 14 days before IMP administration. Exceptions may apply on a case by case basis, if considered not to interfere with the objectives of the study, as determined by the PI
21. Failure to satisfy the investigator of fitness to participate for any other reason

Date of first enrolment
13/01/2020

Date of final enrolment
11/03/2020

Locations

Countries of recruitment
United Kingdom

England

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Sponsor information

Organisation
Quantum Genomics (France)

ROR
https://ror.org/01eyskv76

Funder(s)

Funder type
Industry

Funder Name
Quantum Genomics

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to there being no requirement to do so.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		16/10/2020	24/06/2022	No	No
HRA research summary			28/06/2023	No	No
Protocol file	version 1.0	17/10/2019	12/08/2022	No	No