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A 3-part study in healthy male volunteers to assess the safety and tolerability of the test medicine TQS-168 and how it is taken up by the body when given as single and multiple doses

Submission date
29/09/2021

Recruitment status
No longer recruiting

Registration date
05/10/2021

Overall study status
Completed

Last Edited
12/04/2023

Condition category
Other

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

Plain English summary of protocol

Background and study aims
A Phase 1 drug study looks at how a drug works in the human body and the safety of this drug in healthy volunteers. This trial does not test if the drug helps to improve health.
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 TQS-168 in healthy volunteers.
TQS-168 is an experimental drug (not yet approved by health authorities).

The aims of this study are:
1. To compare how much of the study drug is absorbed and how long it takes to get eliminated in different suspension formulations of TQS-168.
2. To evaluate the effect food has on the absorption of TQS-168 in suspension form.
3. To collect information on any side effects that may occur when TQS-168 is taken with food and /or without food.

Who can participate?
Healthy male volunteers aged 18 to 55 years, inclusive

What does the study involve?
In the single ascending dose part, subjects will be given a single dose of TQS-168 suspension formulations or placebo on Day 1. In the multiple ascending dose part, subjects will be given a single administration of TQS-168 on 7 consecutive days if daily dosing is selected or 13 single administrations over 7 consecutive days if twice daily dosing is selected. If a subject receives TQS-168 or placebo will be determined randomly.

What are the possible benefits and risks of participating?
Participants are not expected to receive any direct benefits from the study, but the information that is learned may help other people in the future. During the study, some side effects

(unwanted effects or health problems) from the study drug or from the study procedures may be experienced. This study will be the first time this test medicine has been given to humans. We therefore do not know the side effects that will occur in humans. The test medicine has been investigated in animals and has not shown any major safety concerns.

Where is the study run from?
Tranquis Therapeutics, Inc (USA)

When is the study starting and how long is it expected to run for?
September 2021 to April 2022

Who is funding the study?
Tranquis Therapeutics, Inc (USA)

Who is the main contact?
Janet Hurt, janet@tranquis.com

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
2021-003069-37

Integrated Research Application System (IRAS)
300388

Protocol serial number
TQS-168-01

Study information

Scientific Title
A Randomized, Double-Blind, Placebo-Controlled, Single-and Multiple-, Ascending-Dose Study of the Safety, Tolerability and Pharmacokinetics of TQS-168 in Healthy Male Adults

Study objectives
To evaluate the relative bioavailability and food effect of TQS-168 in healthy male participants

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 19/08/2021, London - Riverside Research Ethics Committee (Ground Floor, Temple Quay House, 2 The Square, Bristol, BS1 6PN, UK; +44 (0)207 104 8184; riverside.rec@hra.nhs.uk), ref: 21/LO/0513

Primary study design
Interventional

Study design
Phase 1 single-centre blinded randomized placebo-controlled study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Safety and tolerability of the test medicine TQS-168

Interventions
The study consists of a single (Part 1, SAD cohort) and multiple-dose (Part 2, MAD cohort) escalation.

In Part 1 using a computer-generated randomisation schedule, subject numbers will be allocated to either TQS-168 suspension formulation or placebo in a 6:2 ratio. In each cohort, 6 subjects will receive TQS-168 suspension formulation and 2 subjects will receive placebo.
In Part 1, where sentinel dosing is required (Cohorts 1, 2, 3 [Period 1], 4, 5 and 6); the first 2 subjects in each cohort (the sentinel group) will be randomised in a 1:1 ratio between TQS-168 suspension formulation or placebo. The remaining subjects (main group) will then be allocated to TQS-168 suspension formulation or placebo in a 5:1 ratio. Subjects in Cohort 3 Period 2 will retain their original randomised treatment from Period 1.
Duration: treatment 1 day + follow-up up to 14 days (follow-up visit window 10 to 14 days after treatment)

In Part 2 using a computer-generated randomisation schedule, subject numbers will be allocated to either TQS-168 suspension formulation or placebo in an 8:2 ratio. In each cohort, 8 subjects will receive TQS-168 suspension formulation and 2 subjects will receive placebo. If sentinel dosing is required, then this will be reflected in the randomisation schedule i.e., the first 2 subjects in each cohort (the sentinel group) will be randomised in a 1:1 ratio between TQS-168 suspension formulation or placebo and the remaining subjects (main group) will then be allocated to TQS-168 suspension formulation or placebo in a 7:1 ratio.
Duration: treatment 7 days + follow-up up to 14 days (follow-up visit window 10 to 14 days after end of treatment)

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
TQS-168

Primary outcome(s)
To provide safety and tolerability information for TQS-168 by assessing:
1. Adverse events (AEs) measured using subject interviews, physical examination at throughout the study
2. Vital signs measured using Oral temperature at screening and pre-dose. Oral temperature, BP, HR and Respiratory rate at screening, pre-dose and at 1, 2 and 24, 36 and 48 hours post-dose for the SAD cohorts and for MAD cohorts oral temperature, RR, BP and HR at pre-dose, 1 hour, 2 hour and 4 hour post-dose on days 1 to 7 (treatment period) and at 24, 36 and 48 hour after last dose.
3. Electrocardiograms (ECGs) measured at screening, pre-dose and at 1, 2 and 24, 36 and 48 hours post-dose for the SAD cohorts and for MAD cohorts at pre-dose, 1 hour, 2 hour and 4 hour post-dose on days 1 to 7 (treatment period) and at 24, 36 and 48 hour after last dose
4. Physical examinations measured at screening, pre-dose, 24 and 48 hours post-dose and at follow-up visit 10 to 14 days post-dose for the SAD cohorts; For MAD cohorts at screening, pre-dose and 48-hours after last dose (day 9) and at follow-up visit 10 to 14 days following last dose. Targeted symptom driven physical examination will be performed as clinically indicated as per investigator judgement for both SAD and MAD cohorts.
5. Laboratory safety tests:
For SAD cohorts, safety labs – haematology, clinical chemistry and urinalysis will be performed at screening, pre-dose and 48 hours after dosing and at follow-up visit 10 to 14 days following dosing.
For MAD cohorts, safety labs – haematology, clinical chemistry and urinalysis will be performed at Screening, pre-dose on days 1, 2 and 7 and at 24 and 48 hour after the last dose on day 7 and at the follow-up visit 10 to 14 days following the last dose.

Key secondary outcome(s)
PK for TQS-168:
For SAD cohorts PK samples are collected at pre-dose, and at 0.5, 1, 1.5, 2, 3, 4, 6, 8, 10, 12, 16, 24, 36 and 48 hour post-dose.
For MAD cohorts PK samples are collected at following timepoints:
Day 1 at pre-dose, and 0.5, 1, 1.5, 2, 4, 6, 8, 10, 12, 16 and 24-hour post-dose
Day 2 to Day 6 at 2, 4, 24-hours post-dose
Day 7 at 0.5, 1, 1.5, 2, 4, 6, 8, 10, 12, 16, 24, 36, and 48 hours post-dose

Completion date
27/04/2022

Eligibility

Key inclusion criteria
1. Healthy male subjects
2. Aged 18 to 55 years inclusive at the time of signing informed consent
3. Body mass index (BMI) of 18.0 to 32.0 kg/m^2 as measured at screening
4. Weight ≥55 kg at screening

5. Must be willing and able to communicate and participate in the whole study
6. Must provide written informed consent

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Male

Total final enrolment
77

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, or are immediate family members of, a study site or sponsor employee
3. Parts 1 and 2 Only: Subjects who have previously been administered IMP in this study
4. Evidence of current SARS-CoV-2 infection
5. History of any drug or alcohol abuse in the past 2 years
6. Regular alcohol consumption >21 units per week (1 unit = pint beer, or a 25 mL shot of 40% spirit, 1.5 to 2 units = 125 mL glass of wine, depending on type)

Date of first enrolment
09/06/2021

Date of final enrolment
23/03/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Quotient Sciences
Mere Way
Ruddington Fields
Ruddington

Nottingham
United Kingdom
NG11 6JS

Sponsor information

Organisation
Tranquis Therapeutics

Funder(s)

Funder type
Industry

Funder Name
Tranquis Therapeutics

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 participant level data not being regulatory required for Phase 1 study.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No