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A study to evaluate the safety of NTX-1955 in patients with generalised anxiety disorder

Submission date
01/11/2025

Recruitment status
Recruiting

Registration date
06/03/2026

Overall study status
Ongoing

Last Edited
06/03/2026

Condition category
Mental and Behavioural Disorders

[ ] 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 aim of this study is to test the safety and tolerability of an investigational drug called NTX-1955 in adult patients (aged 18-55 years) with generalised anxiety disorder (GAD). NTX-1955 has not been approved for use outside of a research study. NTX-1955 has been tested in healthy volunteers and has been shown to be well-tolerated. This study is now being conducted to test the safety and tolerability of NTX-1955 in a small group of patients with GAD. Researchers will compare the effects of treatment with NTX-1955 to a placebo (a look-alike substance that contains no drug).

Who can participate?
Patients aged 18-55 years with GAD

What does the study involve?
Participants enrolled in this study will need to take a capsule with NTX-1955 (at one of two possible dose levels) or a placebo once a day for 2 weeks. Before patients can be enrolled they will need to attend a screening visit to ensure they are suitable to take part in the study. Following the screening visit, participants will also need to visit the clinic a further five times for check-ups and tests.

What are the possible benefits and risks of participating?
The study drug has been given to healthy participants in three completed studies and in total 98 people have previously taken the study drug. In the previous studies the most common reported side effects were:
1. Confusional state, e.g. complaints related to thinking, learning, and understanding, such as attention problems, disorientation and confusion. The participants will be monitored for any change in attention and orientation.
2. Somnolence/sleepiness.
3. Abnormal liver laboratory results. Blood samples will be analysed for any changes in liver function.
4. Changes to the participant's circulatory system (including heart rate and blood pressure). The participants' heart rate and blood pressure will be checked regularly.
The study drug’s effect on the body may change when the drug is taken in combination with

another drug, which can result in either a decrease or an increase in the effects of either or both drugs. The study doctor will review the participant's medication at the screening visit. Participants will be informed of any medications that they cannot take for the duration of the study.
Risk of contraception failure for female participants: Some oral contraceptives may become less effective when taken with the study medication, as the study medication could affect the way the body processes these contraceptives.
The risks of the study drug medication to an embryo, foetus or nursing infant are unknown. Therefore, female patients who are pregnant or breastfeeding are not eligible to participate in the trial. Male and female participants must agree to follow the contraception requirements as described in the patient information sheet. Participants are informed that if they or their partner becomes pregnant during the study, they should inform the study doctor immediately. Female participants will be required to take a pregnancy test at each visit.
Participants will be informed of the potential risks due to the study medication in the patient information sheet. The participants will be monitored closely for any side effects and will be informed that they should report any side effects as soon as they appear, whether or not they are related to the study medication.
Blood tests: Participants may experience some pain and discomfort when the needle is inserted. There may also be some soreness after the blood has been taken. There may also be some bruising and bleeding at the insertion site. Some people faint or feel light-headed during or after a blood test. Rarely the site of the blood draw may become infected.
12-lead ECG: The participant may find it a little uncomfortable when electrodes are removed from their chest at the end of the recording.
qEEG: A small number of patients have allergic skin reactions. A small number of people are sensitive to flashing lights or deep breathing which may increase the likelihood of having a seizure.
Risks relating to the study procedures and study medication are explained to participants in the patient information sheet and consent form. The participants will be given adequate opportunity to ask the Investigator any questions before consenting to participate. The participants will be informed of any new information that may become available that may affect their willingness to participate. The procedures will only be performed by fully qualified staff.

Where is the study run from?
Newleos Therapeutics (USA)

When is the study starting and how long is it expected to run for?
October 2025 to August 2026

Who is funding the study?
Newleos Therapeutics (USA)

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
1013090

Protocol serial number
NTX-1955-103

Study information

Scientific Title
A multicentre, double-blind, randomised, placebo-controlled trial to evaluate safety and tolerability of NTX-1955 in adult patients with generalised anxiety disorder

Study objectives
The primary objective of the study is to evaluate the safety and tolerability of NTX-1955 following multiple oral doses of either 15 mg or 25 mg of NTX-1955 administered to patients with Generalised Anxiety Disorder (GAD) for 2 weeks.

The secondary objective of the study is to assess the PK of NTX-1955 following multiple oral doses of either 15 mg or 25 mg of NTX-1955 administered to patients with GAD for 2 weeks.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 12/12/2025, Wales REC 1 (-, -, -, United Kingdom; -; Wales.REC1@wales.nhs.uk), ref: -

Study design
Double-blind randomized placebo-controlled parallel-group trial

Primary study design
Interventional

Study type(s)
Safety

Health condition(s) or problem(s) studied
Generalized anxiety disorder (GAD)

Interventions
Participants will be randomised using an Interactive Response Technology (IRT) system to one of the three following treatment arms:
1. 25 mg NTX-1955
2. 15 mg NTX-1955
3. Placebo

Participants in each treatment arm will be required to take one capsule of either 25 mg NTX-1955, 15 mg NTX-1955 or placebo once daily for 14 consecutive days. Participants will attend a follow-up visit 14 days after the last dose.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
NTX-1955

Primary outcome(s)
The safety and tolerability of NTX-1955 measured by the incidence and severity of treatment-emergent adverse events from the first dose until the end of the study

Key secondary outcome(s))
The pharmacokinetics of NTX-1955 measured by the plasma concentrations of NTX-1955 (optionally, a potential metabolite M5) on Day 1, Day 7 and Day 14

Completion date
17/08/2026

Eligibility

Key inclusion criteria
1. Age: 18–55 years (inclusive).
2. Diagnosis: Generalised Anxiety Disorder (DSM-5-TR) confirmed by MINI, with symptoms for ≥6 months before screening.
3. Severity: HAM-A ≥20 at screening.
4. Contraception/pregnancy: Participants of childbearing potential agree to protocol-specified contraception/abstinence for the required period; negative pregnancy test at screening (and baseline/day 1 if applicable); not pregnant or breastfeeding.
5. Body size: BMI 18–35 kg/m² and weight ≥50 kg at screening.
6. Psychotherapy: Counselling/psychotherapy allowed if stable ≥4 weeks pre-Day 1 and expected to remain stable through Day 14; if not in therapy, agrees not to start until after Day 14 visit window.
7. Consent: Able and willing to provide written informed consent and comply with study requirements.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
55 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Primary psychiatric disorder other than GAD that could interfere with study participation /outcomes (per MINI/investigator).
2. Psychotic disorder (lifetime/current), or current PTSD, OCD, or bipolar disorder.
3. Suicidality/safety risk: Recent significant suicidal ideation/behaviour per C-SSRS and/or investigator judges participant a safety risk.
4. Substance/alcohol: Moderate/severe alcohol or substance use disorder within 12 months (DSM-5/MINI), inability to comply with alcohol restrictions, or positive breath alcohol/urine drug screen at screening/baseline.
5. Prohibited concomitant meds: Use of prohibited medications within required washout; specifically moderate/strong CYP3A4 inhibitors/inducers (incl. St John’s Wort) within 28 days or 5 half-lives (whichever longer) before Day 1.
6. Recent investigational product exposure / excessive trial participation: Investigational drug within 60 days or 5 half-lives (whichever is longer) before Day 1; frequent participation as per

protocol limits.
7. Clinically significant medical conditions or abnormal screening findings that increase risk or confound outcomes (including clinically significant abnormalities in labs, ECG, vitals, physical exam), per investigator.
8. Seizure risk/neurologic conditions: Epilepsy/seizure disorder (except uncomplicated febrile convulsions) or neurologic history likely to increase seizure risk or interfere with EEG readouts (e.g., significant TBI, stroke, encephalopathy).
9. Hepatic impairment: Liver enzymes or bilirubin >1.5× ULN.
10. Infections: Positive HBV, HCV, or HIV screening tests.
11. Hypersensitivity/allergy: Known hypersensitivity to benzodiazepines (and other clinically significant allergy/anaphylaxis history as relevant).

Date of first enrolment
28/02/2026

Date of final enrolment
17/07/2026

Locations

Countries of recruitment
United Kingdom

Study participating centre
-
-
-
England
-

Sponsor information

Organisation
Newleos Therapeutics

Funder(s)

Funder type
Industry

Funder Name
Newleos Therapeutics

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date