

A single ascending dose study of TX002100 in healthy participants

ACTRN12626000242325

Status	RECRUITING
Phase	Phase 1
Sponsor	Tectonic Operating Company, Inc.
Enrollment	48 participants

Plain Language Summary

TX002100 is a brand-new investigational medication being tested in humans for the very first time in this study. Before any new drug can be approved for patients, researchers must carefully test it in healthy volunteers to understand how the body absorbs, processes, and tolerates it. This type of study is called a 'first-in-human' trial, and it is designed with safety as the top priority.

Participants will receive a single dose of either TX002100 or a placebo (an inactive substance), and will be closely monitored in a clinical unit for any side effects. Six different dose levels will be tested across separate groups of 8 participants each, with most participants receiving the real drug and a smaller number receiving the placebo. The study will build up the dose gradually to ensure safety at each level.

You may be eligible if you are between 18 and 55 years old, are in good general health, have a healthy BMI (18-32 kg/m²), and have normal heart function on an ECG. Women must be postmenopausal or have had a surgical procedure that prevents pregnancy. Men must agree to use contraception for 90 days after the dose. People with significant medical history, heavy smoking history, or recent infections would not be eligible.

Key Eligibility Criteria

Inclusion (12)

- If male, agrees to use adequate methods of contraception for at least 90 days after dosing, or if female, is of non-childbearing potential by meeting EITHER of the following criteria: a) Is in a postmenopausal state, defined as no menses for 12 months without an alternative medical cause and follicle-stimulating hormone level consistent with postmenopause (greater than or equal to 23 U/L) b) Has a documented hysterectomy, bilateral oophorectomy, or salpingectomy
- Is judged to be in good health based upon medical history, physical examination, vital signs, ECGs, and routine laboratory tests.
- Has a BMI (body mass index) between 18 and 32 kg/m², inclusive, and body weight of at least 55 kg at screening.
- Meets BOTH of the following criteria for the screening ECG and baseline ECGs:
 - a) Has ECG parameters within the normal range, defined as meeting ALL of the following:
... and 7 more (see full listing online)

Exclusion (11)

- Participants are excluded from the study if any of the following criteria apply:
 - Is mentally or legally incapacitated, has significant emotional problems at the time of the study, or has a history of significant psychiatric disorders as determined by the principal investigator or delegate.
 - Has any clinically significant physical examination abnormalities observed during the screening visit or would not be a good candidate for participation in the study in the opinion of the principal investigator or delegate.
 - Has clinically significant abnormal hematology, clinical chemistry, or urine analysis at screening or Day minus 1.
 - Was hospitalized for any reason within thirty days before the screening visit.
- ... and 6 more (see full listing online)

Locations (1 total)

<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12626000242325>

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