

A Phase 1 Study of GTX-B001 in Healthy Subjects and Patients With Chronic Inducible Urticaria

NCT07181369

Status	RECRUITING
Phase	Phase 1
Sponsor	Granular Therapeutics Limited
Enrollment	72 participants

Key Eligibility Criteria

Inclusion (8)

- The subject is between 18 and 55 years of age (both inclusive) at the date of screening.
- The subject is in good general health based on the medical history, physical examination and the results of vital signs, electrocardiogram and clinical laboratory, as judged by the investigator.
- The subject is between 18 and 75 years of age (both inclusive) at the date of screening
- A history of signs and/or symptoms of ColdU or SD experienced e 3 months prior to screening.
- For ColdU patients, a positive provocation test during screening and baseline, using the TempTest® device.

... and 3 more (see full listing online)

Exclusion (9)

- Presence of any clinically significant illness, such as cardiovascular, neurologic, pulmonary, hepatic, renal, metabolic, gastrointestinal, urologic, immunologic, or endocrine disease or disorder that would interfere with the patient's safety or the interpretation of trial results in the judgment of the investigator.
- Treatment with an investigational drug or intervention for any condition within three months of screening, or concurrent participation in another clinical trial in which an investigational drug is administered.
- Treatment with immunomodulating therapy (e.g., intravenous or intramuscular immunoglobulins, systemic corticosteroids, cyclosporine, methotrexate, dapsone, cyclophosphamide, tacrolimus, mycophenolate mofetil, hydroxychloroquine, infliximab, adalimumab, etanercept, etc.) within 4 weeks (or 5 half-lives, whichever is longer) prior to screening.
- Use of any monoclonal antibody or therapeutic protein within 4 weeks (or 5 half-lives, whichever is longer) prior to screening.
- History of anaphylaxis, autoimmune disorders requiring more than topical medication, or asthma requiring regular use of inhaled medication within the past 5 years, unless, in the opinion of the Investigator, the condition is not considered clinically significant and is unlikely to affect subject safety or study outcomes.

... and 4 more (see full listing online)

Locations (2 total)

Charité Research Organization gmbh, Berlin, Germany
Fraunhofer Institute For Translational Medicine And Pharmacology, Berlin, Germany

<https://clinicaltrials.gov/study/NCT07181369>

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