

Study of DONQ52 in Active Celiac Disease

NCT07239336

Status	RECRUITING
Phase	Phase 2
Sponsor	Chugai Pharmaceutical
Enrollment	92 participants

Key Eligibility Criteria

Inclusion (9)

- Body mass index (BMI) of 18 to 40 (kg/m²) at screening.
- Willingness to ingest a gluten-free product and Simulated Inadvertent Gluten Exposure (SIGE) products as per the study protocol.
- History of medically diagnosed, and adequately documented (i.e., included in the participant's medical records), CeD
- Attempting a GFD for at least 12 months prior to the screening visit.
- \- The participants should be instructed not to alter dietary habits including a GFD during the study period.

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

Exclusion (11)

- Participants with documented history (i.e., included in the participant's medical records) of medically diagnosed Refractory Celiac Disease (RCD) or suspected RCD by the investigator.
- History of IgE-mediated reactions to wheat, barley, rye, or other ingredients in gluten-free and SIGE products used in this study (i.e., methylcellulose, and gelatin).
- History of cancer, including hematological malignancy and solid tumors, within 5 years prior to the screening visit, or history of T cell lymphoma or B cell lymphoma ever.
- History of hypersensitivity reactions including anaphylaxis to a biological medical product or any of the excipients.
- Participants who carry the HLA-DQ8 (HLA-DQA1*03 and DQB1*0302) genotype (homozygous or heterozygous).

... and 6 more (see full listing online)

Locations (11 total)

Chandler Clinical Trials, Chandler, Arizona, United States
Scottsdale Clinical Trials, Scottsdale, Arizona, United States
Associates in Gastroenterology, PC, Colorado Springs, Colorado, United States
... and 8 more locations