

# GI Alpha-Gal Study

NCT06268717

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<b>Status</b>	RECRUITING
<b>Phase</b>	Not Applicable
<b>Sponsor</b>	University of North Carolina, Chapel Hill
<b>Enrollment</b>	30 participants

## Key Eligibility Criteria

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### Inclusion (6)

- The subject is at least 18 years of age.
- The subject has a history of gastrointestinal alpha-gal allergy defined by elevated test for  $\alpha$ gal allergy ( $\alpha$ gal IgE  $\geq 0.1$  U/L) due to complaints of either abdominal pain or discomfort, diarrhea, nausea with or without vomiting, or a combination of those complaints, within the last 5 years. The subjects must have experienced one or more of the four symptoms at least once monthly for at least two months. The subjects will fill out a symptom questionnaire of the presence of these four symptoms (abdominal pain or discomfort, diarrhea, nausea, vomiting), frequency and severity (mild, moderate, or severe) for the 3 months prior to diagnosis.
- The subject has experienced symptomatic improvement on a mammalian meat-free diet over at least a month's time, defined by saying "yes" to the following question: "On the alpha-gal avoidant diet, have you had adequate relief of gastrointestinal symptoms?"
- The subject has elevated  $\alpha$ gal IgE titer on screening for the trial if they do not have a positive titer within 6 months of enrollment.
- The subject is willing to not take nonsteroidal anti-inflammatory medications, leukotriene modifiers or steroids 14 days prior to challenge.

... and 1 more (see full listing online)

### Exclusion (14)

- The subject has health conditions that would pose a significant threat in the face of anaphylaxis or treatment for anaphylaxis (e.g., cardiac disease, unstable angina pectoris, arrhythmias).
- The subject is allergic to mannitol.
- If female, the subject is pregnant.
- The subject has a history of chronic GI conditions, including inflammatory bowel disease, celiac disease, chronic pancreatitis with continued symptoms (experience moderate-severe abdominal pain, diarrhea, or nausea/vomiting that occur more frequently than once weekly)
- The subject has diarrhea (one or more loose stools that conform to the container), moderate to severe abdominal pain, or vomiting within 10 days prior to the challenge.

... and 9 more (see full listing online)

## Locations (1 total)

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University of North Carolina at Chapel Hill, Chapel Hill, North Carolina, United States

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<https://clinicaltrials.gov/study/NCT06268717>

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