

IV Gallium Study for Patients With Cystic Fibrosis Who Have NTM (ABATE Study)

NCT04294043

Status	RECRUITING
Phase	Phase 1
Sponsor	Chris Goss
Enrollment	40 participants

Key Eligibility Criteria

Inclusion (26)

- Written informed consent obtained from participant or participant's legal representative
- Be willing and able to adhere to the study visit schedule and other protocol requirements
- All genders e 18 years of age at Visit 1
- Documentation of a CF diagnosis as evidenced by one or more clinical features consistent with the CF phenotype
- Documentation of persistently positive NTM culture results that are positive for the same species or sub-species (either *M. avium* complex, *M. abscessus* complex, or both *M. avium* and *M. abscessus*). Persistently positive cultures are those which meet ONE of the following criteria, after first ignoring any negative culture results that occur within 7 days of a positive culture:
... and 21 more (see full listing online)

Exclusion (41)

- Any of the following abnormal lab values at screening:
 - Hemoglobin ≤ 10 g/dL
 - Platelets $\leq 100,000$ /mm³
 - Absolute neutrophil count ≤ 1500 /mm³
 - Aspartate transaminase (AST), alanine transaminase (ALT), gamma-glutamyl transferase (GGT), alkaline phosphatase (ALP), or total bilirubin ≥ 3 x upper limit of normal
- ... and 36 more (see full listing online)

Locations (10 total)

University of Alabama at Birmingham, Birmingham, Alabama, United States
National Jewish Health, Denver, Colorado, United States
Johns Hopkins University, Baltimore, Maryland, United States
... and 7 more locations

<https://clinicaltrials.gov/study/NCT04294043>

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