

Tocilizumab Discontinuation Versus Dose Reduction for Patients With Well-Controlled Giant Cell Arteritis

NCT07108387

Status	RECRUITING
Phase	Phase 2
Sponsor	National Institute of Allergy and Infectious Diseases (NIAID)
Enrollment	78 participants

Key Eligibility Criteria

Inclusion (13)

- Ability and willingness to provide written informed consent and to comply with the study protocol
- Diagnosis of Giant cell arteritis (GCA) classified according to the following criteria:
 - a. AND at least one of the following:
 - i. Cranial signs or symptoms of GCA (new-onset localized headache, scalp tenderness, temporal artery tenderness or decreased pulsation, ischemia-related vision loss, or otherwise unexplained mouth or jaw pain upon mastication)
 - ii. Symptoms of polymyalgia rheumatica (PMR), defined as shoulder and / or hip girdle pain associated with inflammatory morning stiffness
- ... and 8 more (see full listing online)

Exclusion (30)

- An autoimmune disease or other condition, other than Giant cell arteritis (GCA), that requires/is anticipated to require chronic or recurrent oral or parenteral glucocorticoids or other immunomodulatory therapy. (Topical and inhaled therapies are acceptable)
- Hospitalization within 8 weeks prior to randomization
- Suspected or established adrenal insufficiency
- Treatment with any investigational agent within 12 months of randomization
- Concomitant treatment with another biologic immunosuppressant (e.g., etanercept, adalimumab, infliximab, certolizumab, golimumab, sarilumab, abatacept, rituximab, or secukinumab) within 12 months prior to randomization. Concomitant treatment with non-biologic immunosuppressants (e.g.
- ... and 25 more (see full listing online)

Locations (7 total)

Emory University School of Medicine: Division of Rheumatology, Atlanta, Georgia, United States
Northwestern University, Chicago, Illinois, United States
Johns Hopkins Hospital: Division of Rheumatology Vasculitis Center, Baltimore, Maryland, United States
... and 4 more locations

<https://clinicaltrials.gov/study/NCT07108387>

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