Study of Salvage Therapy to Treat Patients With Granulomatosis With Polyangiitis

NCT04871191

Status	RECRUITING
Phase	Phase 3
Sponsor	Assistance Publique - Hôpitaux de Paris
Enrollment	42 participants

Key Eligibility Criteria

Inclusion (14)

- Newly diagnosed or relapsing granulomatosis with polyangiitis according to American College of Rheumatology criteria, EMA classification algorithm and/or the 2012 revised Chapel Hill Consensus Conference definition.
- Aged 18 years or older
- Active clinical manifestations attributable to GPA
- An inadequate response to previous standard of care therapy including either :
- A combination of glucocorticoids plus cyclophosphamide

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

Exclusion (17)

- An allergy or hypersensitivity to monoclonal antibodies or either of the study drugs (rituximab, abatacept or tocilizumab) or to their excipients
- A previous treatment with a combination of rituximab plus a cDMARD, with tofacitinib, or with tocilizumab
- A contraindication to a combination of rituximab plus a cDMARD, to tofacitinib, or to tocilizumab (including an ongoing infection; history of recent cancer \<5 years before enrollment, except for cured non-melanoma skin cancer); pregnancy; and breastfeeding.
- Patients with severe vasculitis manifestations that requires plasma exchange therapy including severe renal failure with a creatinine level e350 µmol/L or severe alveolar haemorrhage
- Patients with vasculitis in remission

... and 12 more (see full listing online)

Locations (1 total)

Hôpital de la Croix Saint Simon, Paris, France