Efficacy of Tocilizumab in association to steroids in giant cell arteritis with cerebro-vascular involvement patients: French multicentre randomised and placebo-controlled trial, TOGiAS trial

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Sponsor	Assistance Publique – Hôpitaux de Paris
Main objective and primary endpoint	The primary objective is to assess the efficacy of tocilizumab to induce complete remission of GCA with cerebrovascular involvement (clinical and biological) and absence of clinical and MRI ischemic stroke recurrence at 24 weeks. The primary endpoint is composite: complete remission of GCA (clinical, biological) and absence of clinical and MRI ischemic stroke recurrence at 24 weeks.
Population of study participants	All patients will be eligible if they present neurovascular involvement related to GCA (> 60 years) with symptomatic (stroke) or asymptomatic forms (presence of neurovascular involvement on imaging tools without clinical stroke)

Inclusion criteria	- Age > 60 years
	- Diagnosis of
	  o GCA (according to ACR criteria or positive temporal artery biopsy) (de novo and/or relapse)
	  o And neurovascular involvement:
	  ▪ Either Ischemic stroke (including TIA) in the vertebro-basilar or carotid territory (**symptomatic arterial involvement**)
	  ▪ Either PET uptake of vertebral and/or carotid arteries (extra or intra cranial) and/or angioCT or angioMRI showing arterial involvement consistent with vasculitis (**asymptomatic arterial involvement**)

Exclusion criteria	Other proven cause of stroke: atrial fibrillation, significant atheromatous stenosis of carotid or vertebro-basilar arteries Contraindication to and precaution in use of tocilizumab:
Investigational medicinal product(s)	Experimental group : tocilizumab 162mg/0.9mL administered subcutaneously (SC) weekly during 24 weeks
Comparator treatment	Control group : placebo of administered subcutaneously (SC) weekly during 24 weeks
Number of participants included	33 subjects in experimental group and 33 controls in placebo group
Number of centres	Recruiting centres: 10 neurovascular units and 4 internal medicine of region of "Ile De France".