French prospective open label phase II randomized non-comparative study of SC tocilizumab associated with IV pulse steroid versus IV pulse steroid alone for the treatment of acute anterior ischemic optic neuropathy associated with giant cell arteritis: TOCIAON

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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.
Primary objective and assessment criterion	• To determine if induction therapy by 4 subcutaneous tocilizumab injections over one month (every 7 days) in association to conventional steroid regimen could improve ocular outcome in AION related to GCA • The efficacy will be judged at W8 after treatment start, as the occurrence of an increase of two lines or more of visual acuity on the ETDRS chart.
Experimental design	This is a French multicenter interventional randomized non-comparative phase II study, with a Simon 2-stages optimal "design", of SC tocilizumab associated with IV pulse steroid versus IV pulse steroid alone.
Population involved	All patients will be eligible if they have AOIN related to GCA
Inclusion criteria	• Diagnosis of GCA : ACR criteria (annex 1) • AION characterized by sudden and painless loss of vision, accompanied by pallid swelling of the optic disc, of no more than one-week duration • Age of 50 years or older

Non-inclusion criteria	• Other ocular involvements related to GCA (central retinal artery occlusion, posterior ischemic optic neuropathy, transient ocular manifestations, occipital stroke), if not associated with AION • Biological targeting therapy within 3 months preceding the study
Treatment being tested	Tocilizumab will be administrated subcutaneously at W0, W1, W2, W3 at the dose of 162 mg (experimental group)
Number of subjects chosen	58 (or 39, depending of the study results on the first 20 patients)
Number of centers	10 French centers
Research period	Inclusion period : 12 months Study time for each patient: 3 months Total study time : 15 months