

SELECT-GCA STUDY

A multicenter, randomized, double-blind, placebo-controlled study to evaluate the safety and efficacy of **upadacitinib** in subjects with giant cell arteritis (GCA)

Key eligibility criteria

- ≥50 years adults
- History of ESR ≥50 mm/h or CRP ≥2.45 mg/dL
- New onset or relapsing GCA with active disease (ESR ≥30 mm/h or hsCRP ≥1mg/dL) within 6 wk of baseline
- Cranial GCA symptoms or symptoms of PMR
- Initiated treatment with ≥40 mg oral prednisone (or equivalent but no i.v.)
- No prior exposure to JAK inhibitor
- No recurrent or disseminated (even a single episode) herpes zoster / herpes simplex

If eligibility criteria are met



Referral for screening

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Study Schematic

Diagnosis active GCA

within 6-wk

Screening
(up to 35 days)

0wk

BASELINE

52-wk double-blind placebo-controlled

Period 1

3 treatment groups:

- 15mg + CS 26wk taper

- 7.5mg+ CS 26wk taper

- Placebo + CS 52wk taper

52wk

52-wk blinded extension

Period 2

104wk

Eligibility criteria cont.

Concomitant medications

- No live vaccine within 4 weeks
- No prior exposure to any JAK inhibitor
- No treatment with IL-6 inhibitor within 4 weeks
- No exposure of:
 - MTX, HCQ, CsA, AZA, or MMF within 4 weeks
 - Oral CS for conditions other than GCA within 4 weeks or i.v. CS within 4 weeks
 - Abatacept or TNF inhibitors within 8 weeks
 - Ustekinumab within 12 weeks
 - Cell-depleting agents (e.g., anti-CD 20) or alkylating agents including cyclophosphamide within 6 months
- No chronic use of systemic CS for > 3 years or inability to withdraw from CS
- No > 2 courses of systemic CS therapy to treat conditions other than GCA within 1y
- No oral Traditional Chinese Medicines within 4 weeks

Subject history

- No active: TB, HBV, HCV, HIV
- No active infection(s) requiring treatment with parenteral anti-infectives within 30 days
- No recent (within past 6 months) cerebrovascular accident, myocardial infarction, coronary stenting, or other ischemic events unrelated to GCA
- Uncontrolled hypertension
- Previous recipient of an organ transplant
- No GI perforation, diverticulitis or have a significantly increased risk for GI
- No malignancy except for NMSC or localized carcinoma in situ of the cervix