

A5235: Phase II, Randomized, Placebo-Controlled, Double-Blind Study of Minocycline in the Treatment of HIV-Associated Cognitive Impairment

Sponsored by: the ACTG (NIAID) and Neurologic AIDS Research Consortium (NINDS)

Principal Investigator: Dr. Ned Sacktor

IRB Research project Number: NA_00004863

Study Objective: To examine whether minocycline treatment for 24 weeks improves HIV-associated cognitive impairment.

Design: A phase II, randomized, placebo-controlled, double-blind study of minocycline versus matching placebo in the treatment of HIV-infected subjects with cognitive impairment, as determined by neuropsychological testing. Subjects who complete the 24-week double-blind phase will be offered the option to enter Step 2 and participate in a 24-week open-label treatment phase.

Population: HIV-1 infected individuals on a stable antiretroviral regimen with progressive neurocognitive impairment.

Inclusion criteria:

- HIV positive on a stable antiretroviral regimen (which should not include Atazanavir) since the past 16 weeks with no plans of changing the regimen in the next 24 weeks
- Objective/Subjective neurocognitive decline
- 18-65 years of age
- Meets the specified requirements of certain lab values
- If female-non pregnant and not breast feeding
- Willingness for and no contraindications for LPs

Exclusion Criteria:

- Not on Atazanavir
- Current neoplasms
- Severe premorbid psychiatric illness
- Confounding neurological disorders
- CNS infections or neoplasms
- SLE, Thyroid diseases, Breast feeding, any serious illness requiring systemic treatment
- H/O allergy to sensitivity to Minocycline/other tetracyclines
- Use of certain protocol specified drugs within 45 days before entry

Study Evaluations:, Neurological examinations, Neuropsychological test battery administrations, blood and CSF exams (2)

Study visits: Step 1: Six visits after enrollment, approximately 1 month apart.
Step 2: Three visits in six months at varied intervals

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