

MODERATE TO SEVERE CROHNS DISEASE

Summary: A Phase 3b, multi-center, double-blind, placebo-controlled, randomized trial to examine the corticosteroid-sparing effect of certolizumab pegol in patients with moderate to severe crohn's disease.

This is a therapeutic Phase 3b study. Once enrolled into the initial study, a patient may be eligible for entry into an extension study, if they fail to respond or have lost response while enrolled in the main study. The extension is an open label trial where every participant receives certolizumab pegol.

Inclusion Criteria:

1. Men and women, age 18 years or older.
2. A diagnosis of moderate to severe crohn's disease.
3. The patient is a candidate for treatment with prednisone or prednisolone therapy.
4. If the patient is on an immunosuppressant the dose has to have been stable for at least 8 weeks.
5. If the patient is on a 5-ASA, the dose has to have been stable for at least 4 weeks.
6. If female, the patient is either postmenopausal for at least one year, surgically incapable of childbearing or effectively practicing an acceptable method of contraception.

Exclusion Criteria:

1. Patients who were primary non-responders to previous treatment with an anti TNF therapy drug are excluded.
2. On maintenance corticosteroid therapy.
3. Bowel resection within 3 months.
4. Current total parenteral nutrition.
5. Positive stool laboratory results for pathogens
6. Have short bowel syndrome
7. Patients at a high risk of infection.
8. Patients with known concurrent viral hepatitis.
9. Receipt of any vaccination
10. Concurrent malignancy.
11. Any other condition which in the Investigator's judgment would make the patient unsuitable for inclusion in the study.

This criterion is not all-inclusive, for more information please contact.

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