Precise Infliximab Exposure and Pharmacodynamic Control

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 6 years to 22 years old
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria:

1. Written informed consent from the patient (≥18 years old) or from parent/legal guardian if patient is <18 years old
2. Written informed assent from patient when age appropriate
3. Diagnosis of Crohn's disease within the last 90 days (luminal-only or luminal with a perianal fistula or abscess treated with antibiotics for at least 7 days)
4. ≥6 years to ≤22 years of age, anti-TNF naïve and starting infliximab
5. Clinical activity and luminal inflammation, defined by both (1) and (2)

- (1) PCDAI≥10 (<18 years old) or CDAI ≥150 (≥18 years old) in last 60 days before the decision to start infliximab
- (2) SES-CD>6, or SES-CD>3 for isolated ileal disease (or a report of large intestinal ulcerations)* within the last 60 days or a fecal calprotectin >250 µg/g within last 75 days prior to screening
    1. C-reactive protein >1.0 mg/dL in last 30 days and/or fecal calprotectin >250 µg/g within last 75 days prior to screening
    2. Negative TB (tuberculosis) interferon-gamma release test and a negative urine pregnancy test for female patients (if menstruation has started)

Exclusion Criteria:

1. Diagnosis of ulcerative colitis or inflammatory bowel disease-unspecified
2. Prior use of anti-TNF therapy (infliximab, adalimumab, certolizumab pegol, or golimumab)
3. Internal (abdominal/pelvic) penetrating fistula(e) in last 180 days
4. Intra-abdominal abscess/phlegmon/inflammatory mass in the last 180 days
5. Active perianal abscess (receiving oral antibiotics for <7 days)
6. Intestinal stricture (luminal narrowing with pre-stenotic dilation >3 cm) and surgery planned in the next 90 days
7. Have tested positive for Clostridium difficile toxin (stool assay) or other intestinal pathogens within 14 days of screening unless a repeat examination is negative and there are no signs of ongoing infection with that pathogen.
8. Current hospitalization for complications of severe Crohn's disease
9. Planned use of methotrexate or 6-mercaptopurine (azathioprine) during the induction (first 3 doses of infliximab) phase
10. Current ileostomy, colostomy, ileoanal pouch, and/or previous extensive small bowel resection (>35 cm) or any CD surgery planned within the next 90 days
11. History of autoimmune hepatitis, primary sclerosing cholangitis, thyroiditis, or juvenile idiopathic arthritis
12. Treatment with another investigational drug in the last four weeks
13. History of malignancy (including lymphoma or leukemia)
14. Currently receiving treatment for histoplasmosis
15. History of TB, human immunodeficiency virus (HIV), an immunodeficiency syndrome, a central nervous system demyelinating disease, history of heart failure or receiving intravenous antibiotics in last 14 days for any infection
16. Currently pregnant, breast feeding or plans to become pregnant in the next 1 year
17. Inability or failure to provide informed assent/consent
18. Any developmental disabilities that would impede providing assent/consent

Conditions & Interventions

Interventions:
DEVICE: RoadMAB, DRUG: Infliximab
Conditions:
Crohn Disease
Keywords:
Crohn's

More Information

Description:
Approximately 3 million people in the United States are living with inflammatory bowel disease, which includes Crohn's Disease (CD). There are limited treatment options approved for use in children and adults with Crohn's disease. Physicians need better ways to inform decisions on treatment. The main reason for this research study is to determine if a computer program that calculates an individualized dose based on a patient's blood testing results (precision dosing) can better achieve the best possible response to infliximab compared to standard dosing (conventional dosing).

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