RCT01437: Proactive infliximab optimization using a pharmacokinetic dashboard versus standard of care in patients with inflammatory bowel disease: The OPTIMIZE Trial

Status: Recruiting

Eligibility Criteria

Sex: Male or Female
Age Group: Not specified
This study is NOT accepting healthy volunteers

Inclusion Criteria:

1. 16 to 80 years of age 2. diagnosis of moderate to severe Crohn's disease (CD) or Ulcerative colitis 3. physician intends to prescribe infliximab for treatment 4. have not previously taken infliximab

Exclusion Criteria:

1. pregnant or breastfeeding 2. complications of inflammatory bowel disease (IBD) such as abscess, need for ostomy (study staff review) 3. current infection in last 6 months 4. other significant medical conditions (heart, lungs, liver, endocrine etc.)

Conditions & Interventions

Interventions:
Drug: Infliximab
Conditions:
Digestive & Liver Health
Keywords:
Clinics and Surgery Center (CSC), Crohn's disease

More Information

Description: The purpose of this study is to find out if using a computer program (called iDose) to guide infliximab dosing is more effective and safer than using standard infliximab dosing over 52 weeks. All patients in this study will be receiving infliximab as part of their medical care, this study is only looking at two different methods of determining the dose and timing of administration.
Study Contact: Beiqing Wu - wu000948@umn.edu
Principal Investigator: Byron Vaughn
Phase: PHASE4
IRB Number: STUDY00013632