UK Division of Digestive Diseases and Nutrition

Research News

December 02, 2024

1) Fuzion:
Open to Enrollment
Coordinators—Sarah Turner/Minela Suljicic
PI—Deborah Flomenhoft, MD

A Phase 3, Randomized, Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Efficacy and Safety of Guselkumab in Participants with Fistulizing, Perianal Crohn's Disease. Subjects must:

- Have at least one active draining perianal fistula
- Be naïve to biologics, a primary non-responder, secondary non-responder or intolerant to a maximum of 2 classes of biologic agents OR failure to respond to, or tolerate, oral corticosteroids or immunomodulators

Patients will be excluded if:

- They have prior exposure to IL-12/23 or IL-23 agents, with the exception of those who have had limited exposure to ustekinumab at its approved labeled dosage AND have met the required 16-week washout criterion AND have not demonstrated failure or intolerance to ustekinumab
- They have a history of or concurrent rectovaginal fistulas, rectal and/or anal stenosis (unless the participant undergoes surgical dilation prior to baseline), diverting stomas with anastomotic leakage, abscess or collections which are not properly drained
- They have current complications of Crohn's disease, such as symptomatic strictures or stenoses, short gut syndrome, or any other manifestation, that might be anticipated to require surgery, could preclude any fistula evaluation (both clinical and radiological) to assess response to therapy, or would possibly confound the ability to assess the effect of treatment with guselkumab

2) Nativ3:
Open to Enrollment
Coordinators—Sarah Turner/Minela Suljicic
PI—Alla Grigorian, MD

A randomised, double-blind, placebo-controlled, multicentre, Phase 3 study evaluating efficacy and safety of lanifibranor followed by an active treatment extension in adult patients with non-cirrhotic non-alcoholic steatohepatitis (NASH) and fibrosis 2 (F2)/fibrosis 3 (F3) stage of liver fibrosis. Subjects must:

- Have the following upon central biopsy reading process (can use local biopsy if done in last 7 months): diagnosis of NASH according to the Steatosis-Activity-Fibrosis (SAF): a) Steatosis score ≥1 b) Activity score: A3 or A4 c) Fibrosis score: F2 or F3
- Be on a stable dose of medications: GLP1 and statins for 3 months and anti-obesity treatments and vitamin E (if ≥ 400 IU/day) for 6 months prior to the qualifying liver biopsy (and dose must remain stable from time of biopsy until baseline). This list is not exhaustive
- Have no more than 5% weight change for 6 months prior to Screening and between liver biopsy and Baseline

Patients will be excluded if:

- They have documented causes of chronic liver disease other than NASH
- They have an AST <0.60xULN
- They have an LSM <6 kPa by transient elastography
- They have a predisposition to autoimmune liver disease

3) Regulation of Mucosal Healing in Inflammatory Bowel Disease
Target Enrollment: 60
Patients Enrolled: 15
Coordinator—-Syed Adeel Hassan, MD
PI—-Terrence A. Barrett, MD

A prospective, un-blinded trial evaluating molecular mechanisms regulating mitochondrial function and ulcer healing in patients with inflammatory bowel disease (IBD). To qualify, subjects must be:

- Diagnosed Ulcerative Colitis or Crohn's Colitis
- Diagnosed rheumatoid arthritis or psoriatic arthritis

Patients will be excluded if:

- Subjects classified in an anesthesia risk group, ASA Class = 4
- History of bleeding diathesis or coagulopathy
- Stroke or transient neurological attack within the last 6 months
- Pregnant
- Receiving anticoagulants, anti-platelets, steroid medications
- Subject is HIV-positive
- History of total proctocolectomy or systemic chemotherapy within 18 months.
- Having severe COPD, alcoholism, decompensated cirrhosis, opioid dependence, active infection, symptomatic congestive heart failure, unstable angina pectoris, cardiac arrhythmia, chronic renal disease, or psychiatric illness.

4) Regulation of Intestinal Stem Cell Activation in Colitis
Target Enrollment: 3000
Patients Enrolled: 2324
Coordinator—-Syed Adeel Hassan, MD
PI—-Terrence A. Barrett, MD

A non-randomized, uncontrolled study to assess molecular factors regulating intestinal epithelial cell biology in inflammatory bowel disease patients. Subjects must:

- Have a diagnosis of Crohn's Disease or Ulcerative Colitis
- Normal Controls (Non-Inflammatory Bowel Disease)

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Did You Know...

We have several upcoming Crohn's Disease trials that will begin enrolling in soon.
Stay tuned or contact us for more details!

Continuation of Regulation of Intestinal Stem Cell Activation in Colitis

Patients will be excluded if:

- Classified in an anesthesia risk group, ASA class 4
- Have a history of bleeding diathesis or coagulopathy
- Experienced a stroke or transient neurological attack within the last 6 months
- Are pregnant
- Currently on blood thinners (except aspirin)
- HIV Positive

5) Exosome as Biomarkers for Inflammatory Bowel Disease

Target Enrollment: 2000

Patients Enrolled: 1460

Coordinator—-Syed Adeel Hassan, MD

PI—-Terrence A. Barrett, MD

An uncontrolled, non-randomized study to develop a non-invasive blood test to diagnosis and manageinflammatory bowel disease. Specifically, we aim to identify exosomal lipid profiles characteristic of inflammatory bowel disease and determine if this exosomal biomarker profile can be used as a quantitative marker of disease severity. Subjects must:

- Have a diagnosis of Inflammatory Bowel Disease
- Have an ongoing episode of Clostridium Difficile infection
- Have a diagnosis of lung cancer and chronic obstructive pulmonary disease
- Be healthy (normal controls)

Patients will be excluded if:

- HIV positive

If you have a patient who may qualify or be interested in one of our ongoing studies, please contact us:

Sarah — 859-323-6423 or skmatt0@uky.edu

Minela — 859-323-1086 or msu270@uky.edu

Current Research-Closed to Enrollment

***1*) Duet CD:**

Closed to Enrollment

Coordinators—Sarah Turner/Minela Suljicic

PI—Deborah Flomenhoft, MD

A Phase 2b Randomized, Double-blind, Active- and Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Efficacy and Safety of Induction and Maintenance Combination Therapy with Guselkumab and Golimumab in Participants with Moderately to Severely Active Crohn's Disease