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Eligibility Requirements to Participate in the Celiac Clinical Trial

Ages Eligible for Study: 18 Years to 75 Years (Adult, Senior)

Sexes Eligible for Study: All

Accepts Healthy Volunteers: Yes

Criteria

Inclusion Criteria:

- Patients must meet the following criteria for study entry:
- Adult patients with Celiac Disease (CD)
- Without any additional co-morbidities
- Normal renal and hepatic function
- Diagnosis of CD established at least 6 months prior to trial with diagnostic serology, genetic profile, endoscopic appearance and histopathology report In histologic and serologic remission (defined as MARSH 0 and negative anti-tissue transglutaminase, etc.) following a gluten free diet
- Naïve to treatment with vedolizumab
- Able and willing to provide written informed consent
- Eligibility criteria for laboratory profiles - healthy patient normal laboratory reference values
    - WBC 4.5-12.0 k/UL
    - Platelet count- 140-415 k/UL
    - Hemoglobin- 11.0-17.4 %g/dL
    - Renal Function-
    - Creatinine- 0.5-1.3 mg/dL
    - BUN- 5-20 mg/dL
    - Hepatic Function
    - Albumin - 3.3-5.0 g/dL
    - INR- 0.9-1.1
    - AST- 0-37 U/L
    - ALT- 0-40 U/L
    - Total Bilirubin- 0.1-1.3 mg/dL
    - Alk Phos- 35-150 U/L

Exclusion Criteria:

- Patients who meet any of the following criteria will be excluded from study entry:
- Abnormal MARSH score on enrollment histopathology
- Elevated celiac serologies (anti-tissue transglutaminase, etc.)
- Current use of biologics or immunomodulators Adalimumab, infliximab, Ustekinumab, Golimumab, Tocilizumab, Certolizumab, Etanercept, Rituximab, Anakinra, Abatacept, Tofacitinib, Methotrexate, Azathioprine, 6-MP.
- Current use of immunosuppressive therapy including intermittent systemic corticosteroids within two months of vedolizumab induction
- History of intestinal lymphoma (MALToma, etc.)
- History of cancer including hematologic malignancy, solid tumors, carcinoma in situ, etc.
- Pregnant or lactating
- Fertile females will require at least one form of birth control
- Lack of peripheral venous access
- Inability to comply with study protocol, in the opinion of the investigator
- Neurological conditions which may interfere with monitoring for PML
- History of demyelinating disease or history of major neurological disease
- History of alcohol, drug or chemical abuse < 6 months prior to screening
- History of active tuberculosis (TB) or a positive screening test for latent mycobacterium tuberculosis infection
- Positive PPD= > 10 mm or > 5mm in patients on 15 mg or more of prednisone
- History of BCG vaccination should be screened using Quantiferon TB Gold test
- An Indeterminate Quantiferon test will require a chest X-ray to rule out active TB and consultation with an infectious disease specialist to confirm the risk of latent
- TB is low and that patients can be safely enrolled in the trial
- History of recurrent opportunistic infections and/or of severe or disseminated viral infections
- Active autoimmune disease
- Active inflammatory bowel disease

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.