A Phase III, Multicentre, Randomised, Double-Blind Study to Assess the Safety and Efficacy of Emactuzumab vs. Placebo in Subjects with Tenosynovial Giant Cell Tumour

Status: Recruiting

Eligibility Criteria

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

Inclusion Criteria:

- at least 12 years old - diagnosis of local or diffuse TGCT where surgery is not a good option - women who are of child bearing age must agree to use a highly effective method of contraception - see link to clinicaltrials.gov for complete inclusion and exclusion criteria

Exclusion Criteria:

- women who are pregnant or breast feeding - medical conditions, including auto-immune, that require systemic immunosuppression - current or chronic history of liver disease - significant heart disease

Conditions & Interventions

Interventions:
Drug: Emactuzumab, Drug: Placebo
Conditions:
Rare Diseases, Cancer
Keywords:
Clinics and Surgery Center (CSC), bone cancer, joint cancer, Tenosynovial Giant Cell Tumor, TGCT

More Information

Description: We are conducting research on a new drug called emactuzumab. Emactuzumab is a new type of monoclonal antibody. An antibody is a protein produced by the body's immune system to detect harmful substances. A monoclonal antibody is an artificially created protein that acts like a human antibody. Each antibody is specific for a single substance. Emactuzumab antibodies are aimed at blocking a type of protein called "CSF-1 receptors" from being able to work and to stop a tumor from growing. We will also examine how long this response will last, the impact on movement and quality of life. We will also examine whether participants need surgery during treatment with emactuzumab. In this study, we will also examine the safety of emactuzumab.
Study Contact: Keith Skubitz - skubi001@umn.edu
Principal Investigator: Keith Skubitz, MD
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