

Statistical Analysis Plan

Protocol Title:

Investigator-Initiated, Pilot Study Evaluating the Efficacy of Etanercept in Acute Gout

ClinicalTrials.gov #: NCT03636373

Date: 22 Oct 2020

Objectives

This study aimed to demonstrate that targeting tumor necrosis factor (TNF) using etanercept 50 mg subcutaneous injection is efficacious for gout flares.

Methods

The study was designed as a pilot 14-day, randomized, double-blind study comparing etanercept 50 mg subcutaneous to triamcinolone (TA) 40mg intramuscular injections for flares. It aimed to show that patients treated with etanercept do not have worse pain at 72 hours compared to TA.

Statistical analysis- means of continuous variables between arms were compared via Student's t-test or Wilcoxon rank-sum test.