HYDROXYCHLOROQUINE (HCQ) FOR PREVENTION OF ABNORMAL GLUCOSE TOLERANCE AND DIABETES IN RELATIVES AT-RISK FOR TYPE 1 DIABETES MELLITUS (Protocol TN-22)

Status: Recruiting

Eligibility Criteria

Sex: All
Age: 3 Years and over
This study is NOT accepting healthy volunteers

Inclusion Criteria:

1. Participant in TrialNet Pathway to Prevention Study (TN01) 2. Age 3 years or greater at the time of randomization 3. Willing to provide informed consent 4. Normal glucose tolerance by OGTT within 7 weeks (no more than 52 days) of baseline 5. Two or more diabetes-related autoantibodies present on two separate samples 6. Weight of 12 kg or greater at screening 7. If a female participant with reproductive potential, willing to avoid pregnancy and undergo pregnancy testing prior to randomization and at each study visit 8. Anticipated ability to swallow study medication.

Exclusion Criteria:

1. Abnormal Glucose Tolerance or Diabetes 2. History of treatment with insulin or other diabetes therapies 3. Ongoing use of medications known to influence glucose tolerance 4. Ongoing or anticipated future use of medications known to have untoward interactions with hydroxychloroquine 5. Known hypersensitivity to 4-aminoquinoline compounds 6. G6PD deficiency 7. History of retinopathy 8. Have an active infection at time of randomization 9. Have serologic evidence of current or past HIV, Hepatitis B (positive for Hepatitis B core antibody or surface antigen), or Hepatitis C infection 10. Deemed unlikely or unable to comply with the protocol or have any complicating medical issues, including prolonged QT interval, a disease previously or likely in the future to require immunosuppression, or abnormal clinical laboratory results that interfere with study conduct or cause increased risk. 11. Deemed unlikely or unable to comply with the protocol or have any complicating medical issues, including prolonged QT interval, a disease previously or likely in the future to require immunosuppression, or abnormal clinical laboratory results that interfere with study conduct or cause increased risk. 12. Be pregnant or breastfeeding.

Conditions & Interventions

Interventions:
Drug: Hydroxychloroquine, Drug: Placebo
Conditions:
Type1 Diabetes Mellitus
Keywords:
TrialNet

More Information

Description: The study is a 2-arm, double blinded, multicenter, 2:1 randomized, placebo-controlled clinical trial. All participants will receive close monitoring for progression of T1D. Participants will receive hydroxychloroquine or placebo and close monitoring for progression to Stage 2 (abnormal glucose tolerance) or Stage 3 (clinically overt) T1D. To assess the efficacy, safety and mode of action of hydroxychloroquine to prevent progression from Stage 1 to Stage 2 or Stage 3 of T1D.
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Phase: Phase 2
IRB Number: STUDY00004135
System ID: NCT03428945

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