Title

Phase II multi-centre, double-blind, randomised trial of Ustekinumab in adolescents with new-onset type 1 diabetes

Acronym

USTEKID

Principal/Lead Investigator

Prof Colin Dayan
Prof John Gregory

Participating Sites

Noah's Ark Children's Hospital for Wales
University Hospital of Wales

Study Summary

Type 1 diabetes (T1D) occurs when a person's own immune system attacks their insulin producing cells. When newly diagnosed, many T1D patients still have 10-20% of their insulin-producing cells still functioning. Ustekinumab is currently being used for other skin and bowel conditions and works by blocking the body's immune system. This trial will ascertain whether Ustekinumab can delay or stop those remaining insulin-producing cells from being destroyed. If the drug works, it can potentially improve a patient's ability to control their blood sugar levels. We will consent and screen adolescents newly diagnosed T1D (aged 12-18y) to see if they still have insulin-producing cells left. If they do, we will randomise them to receive either Ustekinumab or a placebo (2:1 ratio) and administer seven treatment doses over 44 weeks. We will collect blood and urine samples for testing at study visits, which will where possible coincide with their routine appointments. We will also ask the participant and a nominated parent to complete three quality of life questionnaires. Week 52 will be a follow up appointment at the hospital, after which we will remotely follow up their health status using hospital records for another year. For participants aged 12-15y, we will seek assent from the child and consent from the parent/carer. Participants aged 16-18 will consent for themselves. All females will be asked to take adequate contraceptive protection and we will do pregnancy testing throughout the study visits. The study will be done at hospitals throughout the UK and study visits will coincide where possible with routine visits to the diabetes care team.

UKCTG Number

39676

Study Sponsor

Cardiff University