

ForPatients

by Roche

Type 1 Diabetes Mellitus Type 2 Diabetes Mellitus

A French Study to Evaluate the Usefulness of Implantable Continuous Glucose Monitoring (CGM) Sensor to Improve Glycemic Control in Participants With Diabetes Mellitus.

Trial Status
Completed

Trial Runs In
1 Countries

Trial Identifier
NCT03445065 RD003329

The source of the below information is the publicly available website [ClinicalTrials.gov](https://clinicaltrials.gov). It has been summarised and edited into simpler language.

Trial Summary:

This study will be conducted in France and will evaluate the usefulness of using a long-term subcutaneously inserted continuous glucose monitoring (CGM) sensor (the Eversense XL CGM System) to improve glycemic control in patients with either Type 1 or Type 2 diabetes mellitus under insulin therapy. Participants will be enrolled into one of two cohorts (Cohorts 1 and 2). Cohort 1 will be focused on participants with Type 1 or Type 2 diabetes with hemoglobin A1C (HbA1c) >8%. Cohort 2 will be focused on participants with Type 1 diabetes spending more than 1.5 hours per day with mean glucose <70 mg/dL, including excursions below 54 mg/dL, for at least 28 days. Within each cohort, participants will be randomized in a 2:1 ratio to one of two groups: the Enabled and Control groups, respectively. The Enabled group will be trained to use the CGM system, whereas the Control group will continue with their usual glucose monitoring system (self-monitoring of blood glucose [SMBG] or flash glucose monitoring [FGM]).

Hoffmann-La Roche
Sponsor

N/A
Phase

NCT03445065 RD003329
Trial Identifiers

Eligibility Criteria:

Gender
All

Age
>= 18 Years

Healthy Volunteers
No
