ISRCTN89358739 https://doi.org/10.1186/ISRCTN89358739

A study to evaluate the performance of a continuous glucose monitoring device in people with diabetes

Submission date
15/09/2023

Recruitment status
No longer recruiting

Registration date
18/09/2023

Overall study status
Completed

Last Edited
29/08/2024

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Diabetes is a disease that occurs when the blood sugar, also called blood glucose, is too high. The continuous glucose monitoring (CGM) device is intended for continuous measurement of glucose levels in people with diabetes (PwD) over the entire CGM run time in a non-clinical setting. This device will measure the glucose level in the fluid found in the spaces around cells (interstitial fluid) present under the skin (subcutaneous). A small measuring sensor will be applied into the subcutaneous fatty tissue and will remain there over the entire duration of the study. After application, the sensor will be paired with the respective CGM application (app) on the smartphones which will prompt the participant at regular intervals to enter the collected values of self-monitoring of blood glucose (SMBG) in the app. The main purpose of the study is to determine the performance, accuracy, safety and usability of a CGM device in measuring the glucose levels in PwD.

Who can participate?
Participants with type 1 or insulin-dependent type 2 diabetes mellitus aged at least 18 years.

What does the study involve?
Participants will have to be a part of this study for a maximum of 22 days, not including the screening visit. The study will have four parts:
1. Screening period wherein participants will be informed about investigational devices and the study, and they will undergo various tests to determine if they are eligible to participate in the study.
2. Device application: Eligible participants will have the investigational devices (CGM Sensor) applied to their arms and will receive respective instructions. Participants will be provided with a study smartphone with the CGM mobile app installed and paired with the CGM sensors. Participants will also measure their SMBG values using a blood glucose (BG) meter with test strips, control solution and a device used to obtain samples of blood for glucose testing (lancing device). A participant diary and a participant card for the duration of the study will also be provided.
3. Sampling days (inpatient): The participants will spend several sampling days at the study site.

For comparison measurements, SMBG measurements will be taken with a commercially available BG meter.
4. Routine days (out-patient): Participants will be asked to perform SMBG measurements during routine days. The participants will be asked to use a diary to document physical activity, showering, bathing, any problems that occurred or any other noticeable observation.
5. Follow-up: After sensor removal, all participants will be followed up for any side effects.

What are the possible benefits and risks of participating?
Participation in this study is purely for research purposes and the participants may have no direct clinical benefits from participating in the study. Participants will be adequately compensated for participating in this study.
Participants may have side effects from the device or procedures used in this study. Side effects can be mild to severe and can vary from person to person.
Risks associated with the CGM device: Bleeding, allergic reaction, damage of muscle tissue or mark on the skin due to the device at the site of application, skin irritations, itching or painful skin condition where fluid fills a space between layers of skin (blistering), a harmful effect from very small quantities of a chemical called cobalt in the small tube called cannula in the sensor.
Risk associated with data handling: There is a rare possibility of photos with potentially participant-identifying skin features, e.g., scars, tattoos.

Where is the study run from?
F. Hoffmann-La Roche Ltd (Switzerland)

When is the study starting and how long is it expected to run for?
January 2023 to November 2023

Who is funding the study?
F. Hoffmann-La Roche Ltd (Switzerland)

Who is the main contact?
global-roche-genentech-trials@gene.com

Contact information

Type(s)
Scientific

Contact name
Dr Katrin Müller

Contact details
Building 1, Grenzacherstrasse 124
Basel
Switzerland
CH-4070
+1 (0)888 662 6728
global-roche-genentech-trials@gene.com

Additional identifiers

Protocol serial number

DC000135

Study information

Scientific Title
Medical device study to evaluate the performance of a continuous glucose monitoring device by comparing device-generated data with capillary blood glucose comparison values in people with diabetes over a 14-day wearing period

Study objectives
The main purpose of the study is to determine the performance of a continuous glucose monitoring (CGM) solution.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 08/03/2023, Ethik-Kommission der Landesaerztekammer Baden-Wuerttemberg (Ethics Committee of the State Medical Association of Baden-Wuerttemberg) (Liebknechtstr. 33, Stuttgart, 70565, Germany; +49 (0)711 76989-964; ethikkommission@laek-bw.de), ref: MDR-2023-002

2. Approved 19/04/2023, Ethikkommission der Medizinischen Universität Graz (Ethics Committee of the Medical University of Graz) (Neue Stiftingtalstr. 6, Graz, 8010, Austria; +43 (0)316 385-13928; ethikkommission@medunigraz.at), ref: 35-240 ex 22/23

Primary study design
Observational

Study design
Open-label single-arm prospective non-randomized multi-center study

Study type(s)
Diagnostic, Safety, Efficacy

Health condition(s) or problem(s) studied
Diabetes mellitus

Interventions
Participants will have three CGM sensors applied in both upper arms for continuous measurement of glucose levels in the subcutaneous interstitial fluid. CGM sensors will be paired with a CGM mobile application. Participants will have to enter the self-monitoring of blood glucose (SMBG) values in the CGM app. Participants will use their usual regimen prescribed by their treating physician to manage their diabetes.

Participants will have to be a part of this study for a maximum of 22 days, not including the screening visit. The study will have four parts:
1. Screening period wherein participants will be informed about investigational devices and the study, and they will undergo various tests to determine if they are eligible to participate in the study.

2. Device application: Eligible participants will have the investigational devices (CGM Sensor) applied to their arms and will receive respective instructions. Participants will be provided with a study smartphone with the CGM mobile app installed and paired with the CGM sensors. Participants will also measure their SMBG values using a blood glucose (BG) meter with test strips, control solution and a device used to obtain samples of blood for glucose testing (lancing device). A participant diary and a participant card for the duration of the study will also be provided.
3. Sampling days (inpatient): The participants will spend several sampling days at the study site. For comparison measurements, SMBG measurements will be taken with a commercially available BG meter.
4. Routine days (out-patient): Participants will be asked to perform SMBG measurements during routine days. The participants will be asked to use a diary to document physical activity, showering, bathing, any problems that occurred or any other noticeable observation.
5. Follow-up: After sensor removal, all participants will be followed up for any side effects.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
CGM Device

Primary outcome(s)
1. Performance of the CGM sensor assessed as an agreement rate of >83% falling within ±20 milligrams per decilitre (mg/dL) (<100 mg/dL) and ±20% (≥100 mg/dL) of paired capillary blood glucose values measured using SMBG measurements on multiple days up to Day 14

Key secondary outcome(s)
1. Performance of the CGM sensor assessed as an agreement rate between paired CGM and SMBG values expressed as percentage falling within ±15/15, ±20/20, ±30/30, ±40/40 (mg/dL <100 mg/dL, % ≥100 mg/dL) for different glucose levels/ranges and for periods with stable and dynamic blood glucose levels measured using pairwise comparison on multiple days from Day 1 up to Day 14
2. Overall mean absolute relative difference (MARD) measured based on SMBG values across all CGM sensors, different glucose levels/ranges and for periods with stable and dynamic blood glucose levels from Day 1 up to Day 14
3. Availability of valid glucose values transmitted using CGM sensors measured from Day 1 up to Day 14
4. Consensus error grid (CEG) assessed based on the CGM sensor wear time up to Day 14
5. Comparison between the performance of two CGM sensors assessed as paired absolute relative difference (PARD) in one participant over 10 and 14 days
6. Classification of application pain measured using Numeric Pain Scale (NRS) on Day 1
7. Classification of bleeding after application measured on a scale of “no, mild, moderate, or severe” assessed on Day 1
8. Failure rate of investigational devices reported using device deficiency report from Day 1 up to Day 22
9. Number of adverse events (AEs), serious AEs (SAEs) adverse device effects (ADEs)/serious ADEs (SADEs) reported in accordance with Regulation (EU) 2017/745 on medical devices from Day 1 up to Day 22

10. Usability of the investigational device assessed using questionnaires for participants and the health care professionals (HCPs) on Day 1 and Day 15

Completion date
16/11/2023

Eligibility

Key inclusion criteria
1. Diabetes mellitus type 1 or type 2 with insulin therapy diagnosed at least 12 months prior to screening
2. Participants using automated insulin delivery (AID) systems: Willingness to stop its algorithm during the course of the Sampling Days (SDs)
3. Acceptance to inject insulin or wearing an insulin pump infusion set minimum of 7.5 centimeter (cm) away from the CGM Sensor application site

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
48

Key exclusion criteria
1. Potential participant older than 45 years with all three cardiovascular risks factors (smoker, arterial hypertension, glycated haemoglobin (HbA1c) >9.0%)
2. Serious acute or chronic concomitant disease or an anamnesis which might, in the opinion of the investigator, pose a risk to the participant
3. Severe diabetes related complications
4. Significantly impaired awareness of hypoglycemia
5. Severe hypoglycemia resulting in seizure or loss of consciousness in the three months prior to screening
6. HbA1c >9.5% / 80.3 millimoles per mole (mmol/mol)
7. Hematocrit greater than 10% below the lower limit of normal at screening
8. History of adhesive incompatibility and/or allergy
9. Skin alterations at the insertion sites (e.g., psoriasis vulgaris, scars, lipodystrophy)
10. History of frequent catheter abscesses in the past year associated with insulin pump therapy, as per investigator’s discretion
11. Chronic use of steroids in adrenal suppressive doses, other immuno-modulatory medication

or chemotherapy
12. Anticoagulant treatment and platelet inhibition (with the exception of acetylsalicylic acid, daily dose rate <300 mg), phenprocoumon (e.g., marcumar), novel oral anticoagulants for atrial fibrillation (NOAK) (e.g., dabigatran, rivaroxaban)

Date of first enrolment
22/09/2023

Date of final enrolment
16/11/2023

Locations

Countries of recruitment
Austria

Germany

Study participating centre
Institute for Diabetes Technology (IfDT)
Lise-Meitner-Str. 8/2
Ulm
Germany
89081

Study participating centre
CRS Clinical Research Services Mannheim GmbH
Grenadierstr. 1
Mannheim
Germany
68167

Study participating centre
Medical University Graz
Auenbruggerplatz 15
Graz
Austria
8036

Sponsor information

Organisation

F. Hoffmann-La Roche Ltd

Funder(s)

Funder type
Industry

Funder Name
F. Hoffmann-La Roche

Alternative Name(s)
Hoffman-La Roche, F. Hoffmann-La Roche Ltd.

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Switzerland

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to participant-level data not being a regulatory requirement.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		19/08/2024	29/08/2024	Yes	No