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Study to evaluate the safety, performance and ease of use of a continuous glucose monitoring (CGM) solution in everyday life for people with diabetes

Submission date
24/05/2025

Recruitment status
Recruiting

Registration date
20/06/2025

Overall study status
Ongoing

Last Edited
15/07/2025

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

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 frequent measurement of glucose levels in people with diabetes (PwD). 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 glucose-measuring sensor will be inserted into the subcutaneous fatty tissue and will remain there over the entire duration of the study. After application, the CGM device will be paired with a CGM application (app) on a smartphone. The main purpose of the study is to determine the safety, performance and ease of use of a CGM solution in measuring the glucose levels in PwD.

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

What does the study involve?
Subjects will have to be a part of this study for a maximum of 22 days, not including screening visit. The study will have 4 parts:
1. Screening period of 28 days wherein subjects will be informed about the CGM device and the study, and they will undergo various tests to determine if they are eligible to participate in the study.
2. Device application: On Day 1, eligible subjects insert a CGM device into their arm. Subjects will be provided with a study smartphone with a CGM mobile app installed. The CGM device will be paired with the CGM mobile app.
3. Sampling Days (in-patient): The subjects will spend 3 sampling days at the study site. For comparison measurements, self-monitoring of blood glucose (SMBG) values will be taken with a commercially available BG meter.
4. Routine Days (out-patient): Subjects will be asked to perform SMBG measurements during routine days.

5. Follow up: After sensor removal on Day 15, all subjects will be followed up for any side effects up to Day 22.

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?
Roche Diabetes Care GmbH (Germany)

When is the study starting and how long is it expected to run for?
March 2025 to September 2025

Who is funding the study?
Roche Diabetes Care GmbH (Germany)

Who is the main contact?
Katrin Mueller, katrin.mueller.km3@roche.com

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
RD007379

Study information

Scientific Title
Medical device study to evaluate the safety, performance and usability of a CGM solution in people with type 1 and type 2 diabetes under real-life conditions for a wear-time of 14 days

Study objectives
The main purpose of the study is to determine the safety, performance and usability of a CGM solution.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 16/05/2025, Ethik-Kommission der Landesaerztekammer Baden-Wuerttemberg (Liebknechtstr. 33, Stuttgart, 70565, Germany; +49 711 76989-19; ethikkommission@laek-bw.de), ref: MDR-2025-007-ff

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

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Other

Study type(s)
Diagnostic, Safety, Efficacy

Participant information sheet
No participant information sheet available

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

Interventions
Subjects will insert a CGM device in the upper arm for continuous measurement of glucose levels in the subcutaneous interstitial fluid. The CGM sensor will be paired with a mobile application for

monitoring of glucose information. Throughout the study, subjects are required to frequently measure their SMBG values. Subjects will continue to follow their regular diabetes management regimen as prescribed by their treating physician.

Intervention Type
Device

Pharmaceutical study type(s)
Performance Study

Phase
Not Applicable

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

Primary outcome measure
Performance of the CGM solution assessed as the overall mean absolute relative difference (MARD) based on paired capillary blood glucose values on multiple days up to Day 14

Secondary outcome measures
1. Performance of the CGM solution assessed as the MARD for different glucose levels/ranges and rate of changes based on paired capillary blood glucose values on multiple days up to Day 14
2. Performance of the CGM solution assessed as the MARD per CGM sensor batch based on paired capillary blood glucose values on multiple days up to Day 14
3. Performance of the CGM solution assessed as an agreement rate based on paired capillary blood glucose values expressed as percentage falling within ±20/20 and ±40/40 (mg/dL <100 mg /dL, % ≥100 mg/dL) on multiple days from Day 1 up to Day 14
4. Consensus error grid (CEG) assessed up to Day 14
5. Lag time of the CGM sensor assessed up to Day 14
6. Failure rate of CGM solution and sensor survival rate up to Day 14
7. 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 up to Day 22
8. Usability of the CGM solution assessed using a questionnaire for the subjects on Day 15

Overall study start date
01/03/2025

Completion date
30/09/2025

Eligibility

Key inclusion criteria
1. Diabetes mellitus type 1 or type 2 diagnosed at least 12 months prior to screening
2. If applicable, acceptance to inject insulin or wearing an insulin pump infusion set minimum 7.5 centimetre (cm) away from the CGM sensor application site

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
76

Total final enrolment
76

Key exclusion criteria
1. Serious acute or chronic concomitant disease or an anamnesis which might, in the opinion of the investigator, pose a risk to the participant
2. Severe diabetes related complications
3. Significantly impaired awareness of hypoglycemia
4. Severe hypoglycemia which required the help of another person or resulting in seizure or loss of consciousness in the three months prior to enrolment
5. Acute illness or abnormality interfering with clinical study procedures
6. HbA1c <6.5% / 48 millimoles per mole (mmol/mol), unless achieved by using an insulin pump or automated insulin delivery (AID) system, and HbA1c >9.5 % / 80.3 mmol/mol
7. Hematocrit greater than 10% below the lower limit of normal
8. History of adhesive incompatibility and/or other contact allergies
9. Skin alterations at the application sites (e.g., psoriasis vulgaris, scars, lipodystrophy)
10. 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), within 2 weeks prior to planned application of the study devices and during the course of the clinical study
11. Intake of ascorbic acid (>500 mg total daily dose); methyldopa or supplements with gentisic acid within two days prior to CGM application and during the course of the study

Date of first enrolment
03/07/2025

Date of final enrolment
17/08/2025

Locations

Countries of recruitment
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
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Sponsor information

Organisation
Roche Diabetes Care GmbH

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Sponsor type
Industry

Website
https://www.roche.com/about/

Funder(s)

Funder type
Industry

Funder Name
Roche Diabetes Care GmbH

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date

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 subject-level data not being a regulatory requirement.

IPD sharing plan summary
Not expected to be made available