# Daily Glucose Patterns in the General Population measured through Flash Glucose Sensors

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We aim to describe and identify distinct daily glucose patters (DGP) in the general population that are related to increased risk of diabetes and diabetes related micro- and macro-vascular complications using the flash sensor technology through the...

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Coronary artery disorders |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON51724

**Source**
ToetsingOnline

**Brief title**
FLASH Study

### Condition

- Coronary artery disorders
- Glucose metabolism disorders (incl diabetes mellitus)
- Renal disorders (excl nephropathies)

**Synonym**
(pre-)diabetes, cardiovascular disease

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum

**Source(s) of monetary or material Support:** Ministerie van OC&W,FSL in natura door Abbott;geen andere financiering

## Intervention

**Keyword:** diabetes, Flash sensor, glucose, hyperglycemia

## Outcome measures

### Primary outcome

- Average glucose levels per 24-hours, per week, over the investigation period,

nocturnal, before breakfast.

- Time in range, time above range (high, very high), Time below range.

- Peak glucose levels, peak post-prandial glucose levels, time to peak in

relation to dietary pattern

- Average area under the curve.

- Incidence of prediabetes and diabetes

- Incidence of micro- and macrovascular events (including kidney function

cardiovascular disease and stroke amongst others).

### Secondary outcome

NA

# Study description

### Background summary

Diagnostic criteria for both prediabetes and T2D rely mostly on fasting or past-prandial glucose levels, with a confirmatory test. However, technological advances, such as flash glucose monitoring and continuous real time glucose sensors have now made it possible to asses extensive daily glucose patterns. There is currently no to little information on how characteristics in these daily glucose patterns relate to the risk of progressing to T2D and its long term complications. This information may provide a plethora of insights to

differences between high risk individuals and why some do and some do not show disease progression. This field of research can provide new pathophysiological insights that could ultimately lead to new and improved diagnostic tools and preventive strategies.

### Study objective

We aim to describe and identify distinct daily glucose patters (DGP) in the general population that are related to increased risk of diabetes and diabetes related micro- and macro-vascular complications using the flash sensor technology through the Free Style Libre (FSL).

### Study design

Observational study in the general population. We will apply the FSL (blinded sensor) to participants from the Rotterdam Study for two weeks.

### Study burden and risks

The application of the FSL will be performed during a regular visit at the research center of the Rotterdam Study by one of the research physicians. The risks of physical harm are negligible but include bruising and local allergic reaction to the patch. We will ask participants to return the sensor either in person or by postal service depending on the preference of the participant and whether another visit is already planned in the context of the Rotterdam Study. Contraindications include imaging through MRI, CT-scan or röntgen or a diathermia treatment. The participants will not get any other physical or dietary restrictions and are allowed to perform their daily activities including water activities such as showering and swimming.

## Contacts

**Public**
Selecteer

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**Scientific**
Selecteer

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

Adult participants of the Rotterdam Study (a population based cohort) that provide informed consent to participate.

## Exclusion criteria

Insulin therapy requiring diabetes

# Study design

## Design

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|---|---|
| Study type: | Observational invasive |
| Intervention model: | Other |
| Allocation: | Non-randomized controlled trial |
| Masking: | Open (masking not used) |

**Primary purpose:** Basic science

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 01-04-2023 |

| | |
|---|---|
| Enrollment: | 6000 |
| Type: | Actual |

### Medical products/devices used

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|---|---|
| Registration: | No |

## Ethics review

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| Approved WMO Date: | 21-02-2023 |
| Application type: | First submission |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 28-04-2025 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

| Register | ID |
|---|---|
| CCMO | NL81467.078.22 |