# Sensor for Measuring the blood glucose level as input for the ARtificial pancreas: a sensor validation Trial.

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Glucose metabolism disorders (incl diabetes mellitus) |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON49011

**Source**
ToetsingOnline

**Brief title**
SMART 1

### Condition

- Glucose metabolism disorders (incl diabetes mellitus)

**Synonym**
Diabetes type 1

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Inreda Diabetic B.V.
**Source(s) of monetary or material Support:** Bedrijf: Inreda Diabetic

## Intervention

**Keyword:** Diabetes, Glucose, Sensor, Validation

## Outcome measures

### Primary outcome

Main parameter to express glucose accuracy is the MARD value (mean absolute relative difference between self-monitoring of blood glucose (SMBG) measurements and Guardian Sensor 3 measurements).

### Secondary outcome

Secondary accuracy parameters are:

* Overall percentage of measured glucose values that fall within ± 0.83 mmol/l of a SMBG measurement at a glucose level of < 5.55 mmol/l.

* Overall percentage of measured glucose values that fall within 15% of a SMBG measurement at a glucose level of >5.55 mmol/l.

* Overall percentage of measured glucose values that fall in zone A and B of the Clarke Error Grid.

* PARD value of the Guardian Sensor 3 in combination with the Enlite Sensor.

AP-related outcome parameters are:

* Life-time of the sensors;

* Percentage of time that the sensors are available as input for the algorithm.

Other study parameters are demographic characteristics, weight, length, HbA1c and amount of administered insulin during usual diabetes treatment.

# Study description

### Background summary

Inreda Diabetic BV. (Goor, The Netherlands) developed a bi-hormonal reactive close loop system to automate control glucose regulation in patients with diabetes mellitus type 1. This artificial pancreas (AP) consists of two subcutaneous glycose enzyme sensors with transmitters to measure continuously the blood glucose values and consists of a algorithm to determine the amount of insulin or glucagon to be administered. In the current CE-marked AP, glucose values are measured by Enlite Sensor (Medtronic) in combination with Inreda Diabetic transmitters. In the future, Medtronic will replace the Enlite Sensor by the Guardian Sensor 3 (Medtronic).

### Study objective

The main objective is to determine the accuracy of the Guardian Sensor 3 in combination with the transmitter developed by Inreda Diabetic BV. Secondary objectives are to assess differences in sensor performance parameters between the Guardian Sensor 3 and Enlite Sensor both in combination with Inreda transmitter; to explore AP-related outcomes for both the Guardian Sensor 3 and Enlite Sensor.

### Study design

This study is a single center, prospective, observational, sensor validation trial.

### Intervention

not applicable

### Study burden and risks

There are no major risks associated with this study since the patients will use their usual diabetes therapy during the study. The most prominent risk is that patients may devevlop irritation and redness caused by the plaster to attach the sensors and possibly hematoma or pain from the SMBGs/sensors. The burden of the study is also relatively low. Patients have to visit the CRC only twice and are only asked to perform and register 7 SMBG measurements per day. There are no individual benefits for participating this study.

# Contacts

**Public**
Inreda Diabetic B.V.

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**Scientific**
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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

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

## Inclusion criteria

* Diagnosed with diabetes mellitus type 1;
* Age between 18 and 75 years;
* Willing and able to sign informed consent.

## Exclusion criteria

* BMI > 35 kg/m2;
* Skin condition prohibiting needle insertion;
* Known or suspected problem related to enzyme based glucose sensor usage;
* Use of acetaminophen during the study period;

* Patients who go swimming or visit a sauna during the study period.

# Study design

## Design

**Study type:** Interventional

| | |
|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Other |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 11-11-2020 |
| Enrollment: | 10 |
| Type: | Actual |

## Medical products/devices used

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|---|---|
| Generic name: | transmitter of the Artificial Pancreas |
| Registration: | Yes - CE intended use |

# Ethics review

Approved WMO

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|---|---|
| Date: | 28-09-2020 |
| Application type: | First submission |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |

# 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 | NL74582.091.20 |