# The effect of postoperative glucose control with a basal bolus versus a sliding scale insulin regimen on the incidence of surgical site infections in people with type 2 diabetes mellitus: A multicentre, matched-pair, cluster-randomised controlled trial

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Diabetic complications |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON57124

**Source**
ToetsingOnline

**Brief title**
The GUIDE trial

### Condition

- Diabetic complications
- Infections - pathogen unspecified

**Synonym**

Surgical site infection, wound infection

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Amsterdam UMC
**Source(s) of monetary or material Support:** ZonMW programme 'Goed gebruik Geneesmiddelen' GGG;funding number: 10140022210033

## Intervention

**Keyword:** Basal bolus, Diabetes mellitus, Sliding scale, Surgical site infections

## Outcome measures

### Primary outcome

The incidence of surgical site infections (SSI) within 30 days after surgery, defined by the Centers for Disease Control and prevention (CDC) criteria.

### Secondary outcome

Other hospital-acquired infections, the length of hospital stay, readmission rates at 30 days after surgery, days at home at 30 days after surgery (DAH30), the time in glucose range (3.9-10 mmol/l), time below glucose range (<3.9 mmol/l) and time above glucose range (>10 mmol/l) measured with a blinded continuous glucose monitor (CGM) during the stay in the hospital, adherence to the protocol, health-related quality of life 30 days after surgery (EuroQoL 5D5L), postoperative disability scores 30 days after surgery (WHODAS 2.0) and associated costs from a healthcare and societal perspective (costs per prevented SSI and QALY's gained).

# Study description

## Background summary

People with type 2 diabetes mellitus (PWT2D) are at increased risk of postoperative complications, especially surgical site infections (SSI). It remains unclear whether improvement of in-hospital glucose control reduces the risk of SSI in people with T2D.

## Study objective

The aim is to reduce SSI in PWT2D by implementing a proactive basal-bolus insulin regimen, compared to a widely used reactive sliding scale regimen. It is hypothesised that a proactive basal-bolus insulin regimen targeting glucose levels of 3.9-10 mmol/l will be superior to a reactive sliding scale regimen targeting glucose levels of 3.9-10 mmol/l, leading to a reduction of 50% of SSI*s within the first 30 days after surgery.

## Study design

Investigator-initiated, multicentre, matched-pair, cluster-randomised, controlled superiority trial.

## Intervention

A postoperative basal-bolus insulin regimen (intervention) will be compared to a sliding scale insulin regimen (control).

## Study burden and risks

General trial-related burden:
Participants will receive a blind CGM, i.e. glucose data are masked for the participants and study team, from admission to the ward until discharge from the hospital. In addition, all participants are asked to complete several questionnaires 30 days after surgery.

Intervention group-related burden:
Both regimens are currently used in clinical practice. Therefore, there is no additional trial-related burden depending on the intervention group allocation.

Preliminary studies suggest a benefit of a basal bolus regimen. There is no evidence for an increase of hypoglycaemic events in a basal bolus regimen, compared to a sliding scale regimen. Participants will be monitored and insulin dosage will be adjusted adequately to the measured glucose values by the treatment team. While the risks are low, this trial has a favourable risk-benefit profile for participants. The overall study will provide insight into the effectiveness of glycaemic control on postoperative recovery, with the potential to improve care for all people with diabetes type 2 undergoing

surgery.

## Contacts

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

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

### Inclusion criteria

1. > 18 years old
2. Diagnosed with type 2 diabetes mellitus
3. Undergoing abdominal or vascular surgery
4. Admitted to one of the participating surgical wards
5. Expected duration of stay at least one overnight stay
6. Willing and able to provide informed consent and complete the questionnaires

### Exclusion criteria

1. Diagnosed with type 1 diabetes mellitus
2. Female who is pregnant or breast-feeding.
3. Undergoing a total pancreatectomy or surgery that leads to total insulin deficiency
4. Undergoing bariatric surgery
5. Patients using a continuous insulin pump at home
6. Patients undergoing a necrotectomy/wound debridement from a pre-existent wound

## Study design

### Design

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| Study type: | Interventional |
| Intervention model: | Parallel |
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Treatment |

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 03-01-2025 |
| Enrollment: | 1058 |
| Type: | Actual |

## Ethics review

Approved WMO

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| Date: | 03-10-2024 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |

# 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 | NL86101.018.24 |
| Other | Volgt |