

# The SUGAR-DIP trial; oral medication versus insulin for diabetes in pregnancy

No registrations found.

|                              |                  |
|------------------------------|------------------|
| <b>Ethical review</b>        | Positive opinion |
| <b>Status</b>                | Recruiting       |
| <b>Health condition type</b> | -                |
| <b>Study type</b>            | Interventional   |

## Summary

### ID

NL-OMON25358

### Source

NTR

### Brief title

SUGAR-DIP

### Health condition

Gestational diabetes  
Diabetes gravidarum  
Zwangerschapsdiabetes

## Sponsors and support

**Primary sponsor:** University Medical Center Utrecht

**Source(s) of monetary or material Support:** ZonMw

## Intervention

## Outcome measures

### Primary outcome

Number of infants born large-for-gestational-age (LGA)

### Secondary outcome

- Maternal hypoglycemia
- Primary / secondary caesarean section
- Pregnancy related hypertensive disorders: pregnancy induced hypertension, preeclampsia
- Preterm delivery (<37 weeks of gestation)
- Neonatal hypoglycemia: moderate (serum glucose <2.6 mmol/l), severe (serum glucose <2.0 mmol/l)
- Neonatal hyperbilirubinemia requiring phototherapy
- Neonatal Medium care / NICU admission

## Study description

### Study objective

Oral antidiabetic medication in the form of metformin and if needed supplementary glibenclamide are a safe and effective first choice treatment strategy for gestational diabetes.

### Study design

- Maternal hypoglycemia: study period until 6 weeks postpartum
- Primary / secondary caesarean section: delivery
- Pregnancy related hypertensive disorders: study period until 6 weeks postpartum
- Preterm delivery: delivery
- Neonatal hypoglycemia: delivery until discharge
- Neonatal hyperbilirubinemia requiring phototherapy: delivery until 6 weeks postpartum
- Neonatal Medium care / NICU admission: delivery until 6 weeks postpartum
- fetal umbilical cord blood C-peptide: delivery
- maternal HbA1c measures: study intake, week 30 and 35 of pregnancy

### Intervention

2 - The SUGAR-DIP trial; oral medication versus insulin for diabetes in pregnancy 3-05-2025

Intervention: metformin and if needed supplementary glibenclamide

Comparator: insulin

## Contacts

### **Public**

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### **Scientific**

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## Eligibility criteria

### **Inclusion criteria**

- Aged 18 years or over
- Singleton pregnancy
- Diagnosis of GDM as per national guidelines
- Indication for pharmacological treatment of GDM
- Gestational age between 16 and 34 weeks
- Ability to understand Dutch or English

- Ability to provide written informed consent

## Exclusion criteria

- Known pre-existent type 1 or type 2 diabetes mellitus
- Severe medical or psychiatric comorbidities
- Serious liver disease or kidney failure, or any other condition with contraindications for the use of either metformin or glibenclamide
- Pregnancy with a fetus affected by major congenital birth defects and/or chromosomal abnormalities

## Study design

### Design

|                     |                             |
|---------------------|-----------------------------|
| Study type:         | Interventional              |
| Intervention model: | Parallel                    |
| Allocation:         | Randomized controlled trial |
| Masking:            | Open (masking not used)     |
| Control:            | Active                      |

### Recruitment

|                           |             |
|---------------------------|-------------|
| NL                        |             |
| Recruitment status:       | Recruiting  |
| Start date (anticipated): | 29-11-2016  |
| Enrollment:               | 810         |
| Type:                     | Anticipated |

## Ethics review

|                   |                  |
|-------------------|------------------|
| Positive opinion  |                  |
| Date:             | 29-11-2016       |
| Application type: | First submission |

## Study registrations

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

ID: 47522

Bron: ToetsingOnline

Titel:

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

No registrations found.

### In other registers

| Register | ID             |
|----------|----------------|
| NTR-new  | NL5953         |
| NTR-old  | NTR6134        |
| CCMO     | NL57195.041.16 |
| OMON     | NL-OMON47522   |

## Study results