# Insulin combination therapy in type 2 diabetes.

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruitment stopped |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON27312

**Source**
Nationaal Trial Register

**Brief title**
DIASULIN

**Health condition**

Diabetes mellitus type 2

### Sponsors and support

**Primary sponsor:** De Stichting Julius Research
**Source(s) of monetary or material Support:** Sanofi-Aventis (Investigator-Initiated-Trial)

### Intervention

### Outcome measures

**Primary outcome**

Difference between the two groups in the remaining insulin secretion of the beta-cells, assessed by the difference in HOMA-beta and in fasting C-peptide.

**Secondary outcome**

1. Difference in mean daily dosage of insulin glargine in order to reach good glycaemic control (HbA1c <= 7,0%);

2. Percentage of patients with good glycaemic control after 12 months;

3. Percentage of patients with good glycaemic controle at several intervals within 12 months;

4. Frequency of serious and of nocturnal hypoglycaemic episodes;

5. Waist circumference;

6. Quality of life;

7. Patients' treatment satisfaction.

# Study description

### Background summary

The purpose of this study is to investigate the effect of continuing sulfonylurea with a combination of metformin and insulin glargine versus discontinuing sulfonylurea with this combination in insulin naïve patients in primary care. We investigate several aspects: remaining insulin secretion of beta-cells, mean daily dosage of insulin glargine, percentage of patients with good glycaemic control at several time intervals, frequency of nocturnal and serious hypoglycaemic episodes, waist circumference, quality of life and treatment satisfaction.

### Study objective

Continuing sulfonylurea in patients without good glycaemic control and using insulin and metformin, will diminish insulin secretion of beta-cells less than discontinuing sulfonylurea in these patients.

### Study design

N/A

### Intervention

Continuing sulfonylurea with a combination of metformin and insulin glargine versus discontinuing sulfonylurea with this combination.

# Contacts

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# Eligibility criteria

## Inclusion criteria

1. Type 2 diabetes patients, male and female, insulin naive, without good glycaemic control for at least 3 months despite combination of metformin and sulfonylurea therapy and who are refererred for insulin therapy by their GP;

2. Age: 40-75 years;

3. HbA1c >=7,5%.

## Exclusion criteria

1. Type 1 diabetes;

2. C-peptide < 0,50 nmol/l;

3. Liver (ASAT/ALAT >2 times normal) and/or kidney (creatinin >135 male, > 110 female) problems;

4. Patients who do not read Dutch good enough to answer questionnaires;

5. Pregnancy/lactation;

6. Amputation (leg, arm);

7. Intercurrent disease at the discretion of the investigator;

8. Short life expectancy;

9. Contraindications/intolerancies for metformin, sulfonylurea or insulin glargine.

# Study design

## Design

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

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-04-2006 |
| Enrollment: | 200 |
| Type: | Actual |

# Ethics review

Positive opinion

| | |
|---|---|
| Date: | 19-04-2006 |
| Application type: | First submission |

# 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 |
|---|---|
| NTR-new | NL604 |
| NTR-old | NTR660 |
| Other | : N/A |
| ISRCTN | ISRCTN29335793 |

# Study results

**Summary results**
N/A