

# Realisation off established targets at patients with diabetes type 2 at primary care setting.

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-OMON25745

### Source

NTR

### Brief title

Feistritz-trial

### Health condition

diabetes type II

## Sponsors and support

**Primary sponsor:** Aventis Pharma(primair)

GSK

BMS

Merck

**Source(s) of monetary or material Support:** n.a.

## Intervention

## Outcome measures

### Primary outcome

The total amount of targets reached with treatment with Rosiglitazone compared with treatment with no Rosiglitazone.

### **Secondary outcome**

The outcome of glitazone to the recent discovered riskfactors of diabetic patients.

## **Study description**

### **Background summary**

N/A

### **Study objective**

Targets of blood pressure, glucose and cholesterol are better feasible with rosiglitazone and structured treatment advice.

### **Intervention**

Two treatmentarms:

Arm A: Addition of Rosiglitazone 8 mg od or

Arm B: No addition of Rosiglitazone

For each patient a regiment of treatment will be arranged concerning the glucose, bloodpressure en cholesterol targets.

## **Contacts**

### **Public**

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### **Scientific**

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## Eligibility criteria

### Inclusion criteria

1. Patients with type 2 diabetes;
2. Signed informed consent.

### Exclusion criteria

1. Age < 18 years;
2. QALY < 5 Years;
3. Use off insulin, fibrates or thiazolidines < 6 weeks before inclusion;
4. Heartfailure, NYHA class II or more;
5. MI, AP, TIA or CVA < 3 months before randomisation;
6. Surgery, severe trauma or infection < 3 months before randomisation;
7. Known liver disease or ALT, AST, gamma GT > 3 times upper limit;
8. Serum creatinine > 150 mmol/l;
9. Triglyceriden > 8 mmol/l.

## Study design

## Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Placebo

## Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-12-2003
Enrollment:	500
Type:	Anticipated

## Ethics review

Positive opinion	
Date:	13-09-2005
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	NL352
NTR-old	NTR391

**Register**

Other  
ISRCTN

**ID**

: N/A  
ISRCTN18435077

## Study results

**Summary results**

N/A