

# Long term double blind comparison of gliclazide modified release and an oral anti-diabetic given in combination with metformin in type two diabetic patients: a two year international, multicentre, randomised, double-blind, parallel-group study followed by a two year double blind extension

|                                        |                                                                |                                                      |
|----------------------------------------|----------------------------------------------------------------|------------------------------------------------------|
| <b>Submission date</b><br>17/11/2006   | <b>Recruitment status</b><br>Stopped                           | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>06/12/2006 | <b>Overall study status</b><br>Stopped                         | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>06/11/2019       | <b>Condition category</b><br>Nutritional, Metabolic, Endocrine | <input type="checkbox"/> Statistical analysis plan   |
|                                        |                                                                | <input checked="" type="checkbox"/> Results          |
|                                        |                                                                | <input type="checkbox"/> Individual participant data |
|                                        |                                                                | <input type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

Not provided at time of registration and not expected to be available in the future

## Contact information

### Type(s)

Scientific

### Contact name

Prof Stefano Del Prato

### Contact details

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## Additional identifiers

## Clinical Trials Information System (CTIS)

2006-001240-30

### Protocol serial number

CL3-05702-013

## Study information

### Scientific Title

Long term double blind comparison of gliclazide MR (30 to 120 mg daily per os) and rosiglitazone (4 to 8 mg daily per os) given in combination with metformin in type 2 diabetic patients. A 2-year international, multicentre, randomised, double-blind, parallel-group study followed by a 2-year double blind extension. - ENDORSE

### Acronym

ENDORSE

### Study objectives

To compare the efficacy of the two bi-therapies administered at optimal dosage on mean weighted HbA1c over two years.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Positive opinion from local ethics committee (Comités de Consultation pour la Protection des Personnes se prêtant à la Recherche Biomédicale [CCPPRB] Hôpital Robert Ballanger, Aulnay sous Bois, France) on 28/07/2006, ref: MCF-22/2006

### Study design

Prospective randomised double blind parallel group comparative phase III trial.

### Primary study design

Interventional

### Study type(s)

Treatment

### Health condition(s) or problem(s) studied

Type 2 diabetes

### Interventions

Please note that as of 02/12/10 the status of this trial has been changed to "Stopped". Following the publication on rosiglitazone cardiovascular safety by Nissen in May 2007 and the European Medicines Agency (EMA) review in October 2007 on the benefits and risks of rosiglitazone and pioglitazone, the recruitment of the ENDORSE study (gliclazide MR versus rosiglitazone, on top of metformin) became no longer feasible and the study was prematurely stopped (last visit patient on 12 March 2008).

Gliclazide Modified Release (MR) versus an oral anti-diabetic on top of metformin.

**Intervention Type**

Drug

**Phase**

Phase III

**Drug/device/biological/vaccine name(s)**

Gliclazide Modified Release (MR), metformin

**Primary outcome(s)**

Change of HbA1c

**Key secondary outcome(s)**

1. Change of other metabolic parameters (Fasting Plasma Glucose, Insulin, Lipids)
2. Assessment of the safety and acceptability profile

**Completion date**

12/03/2008

**Reason abandoned (if study stopped)**

Objectives no longer viable

**Eligibility****Key inclusion criteria**

1. Type 2 diabetic outpatients
2. Male or female aged more than 35 years inclusive
3. Body Mass Index (BMI) 24-38 kg/m<sup>2</sup> inclusive
4. Treated in monotherapy with metformin

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Key exclusion criteria**

1. Type 1 diabetes
2. Recent major cardiovascular events
3. Uncontrolled and clinically significant diseases
4. Insulin therapy
5. Severe and unstable diabetic complications

**Date of first enrolment**

06/11/2006

**Date of final enrolment**

04/12/2007

## **Locations**

**Countries of recruitment**

United Kingdom

Australia

Austria

Belgium

Bulgaria

Canada

Czech Republic

France

Germany

Hungary

Italy

Latvia

Lithuania

Netherlands

Poland

Portugal

Romania

Russian Federation

Slovakia

Slovenia

Spain

**Study participating centre**  
Department of Endocrinology and Metabolism  
Pisa  
Italy  
56124

## Sponsor information

**Organisation**  
Institut de Recherches Internationales Servier (France)

**ROR**  
<https://ror.org/034e7c066>

## Funder(s)

**Funder type**  
Industry

**Funder Name**  
Institut de Recherches Internationales Servier (France)

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from <https://clinicaltrials.servier.com/> if a Marketing Authorisation has been granted after 2014.

### IPD sharing plan summary

Available on request

### Study outputs

| Output type                   | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|-------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Basic results</a> |         |              |            | No             | No              |