

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

Submission date 17/11/2006	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered
Registration date 06/12/2006	Overall study status Stopped	<input type="checkbox"/> Protocol
Last Edited 06/11/2019	Condition category 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

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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/m² 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?
Basic results				No	No