Long term double blind comparison of gliclazide modified release and an oral antidiabetic 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	Recruitment status Stopped	Prospectively registered	
17/11/2006		Protocol	
Registration date	Overall study status	Statistical analysis plan	
06/12/2006	Stopped	[X] Results	
Last Edited 06/11/2019	Condition category Nutritional, Metabolic, Endocrine	Individual participant data	
		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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Contact details

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Additional identifiers

EudraCT/CTIS number

2006-001240-30

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 (EMEA) 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 measure

Change of HbA1c

Secondary outcome measures

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

Overall study start date

06/11/2006

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
Age group Adult
Sex Both
Target number of participants 2500
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 Australia
Austria
Belgium
Bulgaria
Canada
Czech Republic
France
Germany
Hungary
Italy
Latvia
Lithuania

Poland
Portugal
Romania
Russian Federation
Slovakia
Slovenia
Spain
United Kingdom
Study participating centre Department of Endocrinology and Metabolism Pisa Italy 56124
Sponsor information
Sponsor information Organisation Institut de Recherches Internationales Servier (France)
Organisation
Organisation Institut de Recherches Internationales Servier (France) Sponsor details 50 rue Carnot Suresnes France
Organisation Institut de Recherches Internationales Servier (France) Sponsor details 50 rue Carnot Suresnes France 92284 Sponsor type

Netherlands

Funder(s)

Funder type

Industry

Funder Name

Institut de Recherches Internationales Servier (France)

Results and Publications

Publication and dissemination plan

Current version as of 28/03/2018:

Summary results are published in https://clinicaltrials.servier.com.

For interventional Phase III studies ending after the 1st January 2014, the results are/will be published in scientific literature.

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 1st January 2014.

Previous version as of 24/01/2018:

Publication plan:

All phases - Interventional studies ending before 01/10/2018: Summary results will be published on https://clinicaltrials.servier.com/ within 12 months after the end of the study.

All phases - Interventional studies ending after 01/10/2018: Summary results and a lay summary will be published on https://clinicaltrials.servier.com/ within 12 months after the end of the study.

Phase 3 only - The results will be published in scientific literature within 18 months after the end of the study.

Intention to publish date

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