ISRCTN67790431 https://doi.org/10.1186/ISRCTN67790431

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

Registration date
06/12/2006

Overall study status
Stopped

Last Edited
06/11/2019

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
Prof Stefano Del Prato

Contact details
Department of Endocrinology and Metabolism
Section Diabetes
Ospedale Cisanello
Via Paradisa 2
Pisa
Italy
56124

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/m^2 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

Netherlands

Poland

Portugal

Romania

Russian Federation

Slovakia

Slovenia

Spain

United Kingdom

Study participating centre
Department of Endocrinology and Metabolism
Pisa
Italy
56124

Sponsor information

Organisation
Institut de Recherches Internationales Servier (France)

Sponsor details
50 rue Carnot
Suresnes
France
92284

Sponsor type
Industry

Website
http://www.servier.com/

ROR
https://ror.org/034e7c066

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