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A one-year multicentre, international, randomised, double-blind study with comparison of benfluorex versus an oral anti-diabetic in combination with sulfonylurea administered orally for the treatment of type two diabetes

Submission date	Recruitment status	[_] Prospectively registered
20/06/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
11/07/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
17/04/2018	Nutritional, Metabolic, Endocrine	

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

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Additional identifiers

EudraCT/CTIS number
2005-004798-60

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CL3-00780-148

Study information

Scientific Title
A one-year multicentre, international, randomised, double-blind study with comparison of benfluorex versus an oral anti-diabetic in combination with sulfonylurea administered orally for the treatment of type two diabetes

Study objectives
The aim of this study is to demonstrate the non inferiority of the combination of benfluorex plus sulfonylurea compared to the combination of an oral anti-diabetic plus sulfonylurea on the evolution of Haemoglobin A1c (HbA1c) over one year of treatment.

Please note that as of 29/11/2012, the target number of participants for this trial was updated from 1000 to 847

Ethics approval required
Old ethics approval format

Ethics approval(s)
First Ethics Committee approval in France obtained on 08/12/2005

Study design
Double-blind, randomised, parallel group, comparative study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

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
Group one: S00780 (benfluorex), and sulfonylurea
Group two: oral antidiabetic and sulfonylurea

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
S00780 (benfluorex), sulfonylurea.

Primary outcome measure
Evolution of HbA1c over one year of treatment.

Secondary outcome measures
Other efficacy and safety criteria.

Overall study start date
15/01/2006

Completion date
01/02/2008

Eligibility

Key inclusion criteria
1. Male or female aged between 35 and 80 years
2. Body mass index (BMI) between 25 and 45 kg/m2
3. Treated in monotherapy with sulfonylurea
4. Presenting type 2 diabetes

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
847

Key exclusion criteria
1. Type 1 diabetes
2. Known latent autoimmune diabetes in adults

Date of first enrolment

15/01/2006

Date of final enrolment
01/02/2008

Locations

Countries of recruitment
France

Study participating centre
Hôpital Cardio-vasculaire et Pneumologie Louis Pradel
Lyon Cedex 3
France
69394

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 on 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
Results article	results	01/10/2012		Yes	No