

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 20/06/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 11/07/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 17/04/2018	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

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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69394

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

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