

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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Additional identifiers

Clinical Trials Information System (CTIS)

2005-004798-60

Protocol serial number

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

Study type(s)

Treatment

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(s)

Evolution of HbA1c over one year of treatment.

Key secondary outcome(s)

Other efficacy and safety criteria.

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

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?
Results article	results	01/10/2012		Yes	No
Basic results				No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes