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A study to assess the release profiles from fixed combination tablets (gliclazide MR/metformin)

Submission date 31/08/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 17/09/2010	**Overall study status** Completed	
Last Edited 09/05/2023	**Condition category** 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

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PKH-05720-001

Study information

Scientific Title
A study to assess the release profiles from fixed combination tablets (gliclazide MR/metformin)

Study objectives
To compare the release profiles from three fixed combination tablets (gliclazide MR 60 mg metformin) with the free combination and with a 60 mg gliclazide oral solution.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval was obtained before recruitment of the first participants

Study design
Open-label, modified randomised four-way crossover study

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
Five periods, single administration: one oral solution of 60 mg gliclazide, three different gliclazide MR 60 mg - metformin fixed tablet combinations and free combination (gliclazide MR 60 mg and metformin) tablets.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
Gliclazide MR, metformin

Primary outcome measure

Determination of the plasma gliclazide and metformin concentration-time data

Secondary outcome measures
1. Adverse events (at all visits)
2. Physical examination (at all visits)
3. 12-lead ECG (at ASSE visit and at the end-of-study visit)
4. Biochemistry and haematology (at ASSE visit, at D1 and at the end-of-study visit)

Overall study start date
13/09/2010

Completion date
30/11/2010

Eligibility

Key inclusion criteria
1. Healthy male volunteers between the ages of 18 - 40 years inclusive
2. Normal clinical examination

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
12 completed subjects as a minimum

Key exclusion criteria
Clinically significant abnormality in laboratory screening, including haematology, blood biochemistry and urinalysis

Date of first enrolment
13/09/2010

Date of final enrolment
30/11/2010

Locations

Countries of recruitment
Australia

Study participating centre
Nucleus Network
Melbourne
Australia
VIC 3004

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
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.

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 1st January 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