

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

Registration date
17/09/2010

Overall study status
Completed

Statistical analysis plan

Results

Last Edited
09/05/2023

Condition category
Nutritional, Metabolic, Endocrine

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

Prof Peter Hodsman

Contact details

Nucleus Network
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Australia
VIC 3004

Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

Determination of the plasma gliclazide and metformin concentration-time data

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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)

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 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