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

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

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes