

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

|  |  |  |
|--|--|--|
| <b>Submission date</b><br>31/08/2010   | <b>Recruitment status</b><br>No longer recruiting              | <input type="checkbox"/> Prospectively registered    |
|  |  | <input type="checkbox"/> Protocol                    |
| <b>Registration date</b><br>17/09/2010 | <b>Overall study status</b><br>Completed                       | <input type="checkbox"/> Statistical analysis plan   |
|  |  | <input checked="" type="checkbox"/> Results          |
| <b>Last Edited</b><br>09/05/2023       | <b>Condition category</b><br>Nutritional, Metabolic, Endocrine | <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

Prof Peter Hodsman

### Contact details

Nucleus Network  
5th Floor Burnet Tower, AMREP  
Precinct, 89 Commercial road  
Melbourne  
Australia  
VIC 3004

## 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? |
|-------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Basic results</a> |         |              |            | No             | No              |