# A HUMAN (PHASE 0) SINGLE MICRODOSE METABOLIC PROFILING STUDY OF [14C]-GMC-252 IN HEALTHY MALE SUBJECTS

Published: 03-09-2010
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to confirm that GMC 252 is absorbed in humansto determine in humans whether GMC 252 is cleaved, yielding diflunisal and N-acetylcysteine (NAC)to determine whether additional metabolites are formed with GMC-252 compared with diflunisal and NAC

| | |
|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Glucose metabolism disorders (incl diabetes mellitus) |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON34475

**Source**
ToetsingOnline

**Brief title**
[14C]-GMC-252 microdose study

### Condition

- Glucose metabolism disorders (incl diabetes mellitus)

**Synonym**
diabetes, Diabetes Mellitus Type 2

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** PRA International EDS
**Source(s) of monetary or material Support:** Farmaceutische industrie

## Intervention

**Keyword:** Diabetes Mellitus type 2, Diflunisal, GMC-252, N-acetylcysteine

## Outcome measures

### Primary outcome

Pharmacokinetics

Metabolic profiling

Safety

### Secondary outcome

na

# Study description

### Background summary

The drug to be given GMC-252 is a new, investigational compound that may eventually be used for the treatment of Diabetes Mellitus Type II. GMC-252 is a chemical structure that combines the chemical properties of diflunisal and N-acetylcysteine, a combination which is known to effectively treat Diabetes Mellitus Type II in pre-clinical studies. Diflunisal is a known drug with anti-inflammatory activity. N-acetylcysteine is a known drug with antioxidant activity. This chemical combination is expected to be more effective and safe than the combination of the two separate drugs.

### Study objective

to confirm that GMC 252 is absorbed in humans
to determine in humans whether GMC 252 is cleaved, yielding diflunisal and N-acetylcysteine (NAC)
to determine whether additional metabolites are formed with GMC-252 compared with diflunisal and NAC

### Study design

Design:
An open-label, non-randomised study.

Procedures and assessments
Screening:
Medical history, demographic data (including body weight and height), clinical laboratory, alcohol and drug screen,
HBsAg, anti HCV, anti-HIV 1/2, vital signs, 12-lead electrocardiogram (ECG), physical examination, adverse events from
the signing of the Informed Consent Form, previous and concomitant medication.

Admission:
Drug and alcohol screen, AEs and concomitant medication.

Study drug administration:
Period 1: 60 micropgram [14C]-diflunisal and 40 microgram [14C]-NAC (stabilised with EDTA)
Period 2: 100 microgram [14C]-GMC-252 lysine salt

Follow-up:
Clinical laboratory, vital signs, ECG, physical examination, AEs and concomitant medication.

Observation period:
For both periods up to 72 h after drug administration

Blood sampling:
for PK and metabolic profiling of the studydrug and for total radioactivity in plasma: up to 72 h post-dose

Urine sampling:
- for PK and metabolic profiling of the studydrug and for total radioactivity in urine: up to 48-72 h post-dose

Safety assessments:
AEs: recorded from the time the Informed Consent Form is signed until completion of the final visit; concomitant
medication; clinical laboratory: screening, each period at pre-dose and at 72 h post-dose and at the follow-up visit; vital
signs: each period at pre-dose and up to 72 h post-dose; 12 lead ECG: each period at pre-dose and up to 72 h post-dose
and at the follow-up visit; physical examination: at screening and at the follow-up visit.

Bioanalysis:
Analysis of plasma and urine samples for the studydrug and total radioactivity by the Sponsor using a validated
accelerator mass spectrometry (AMS) method.

**Study burden and risks**

Procedures: pain, light bleeding, heamatoma, possibly an infection.

# Contacts

**Public**
PRA International EDS

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9471 GP Zuidlaren
NL
**Scientific**
PRA International EDS

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

healthy male volunteers
- age between 18 and 55 years
- BMI is between 18 and 35 kg/m2
- non smoker or light or moderate smoker, i.e. * 10 cigarettes a day
- at screening the state of health must satisfy the entry requirements

## Exclusion criteria

- Participation in a clinical trial within the previous 60 days prior to drug administration.
- Participation in a clinical trial involving the administration of a [14C]-labelled compound within the previous 6 months prior to drug administration.
- Evidence of clinically relevant pathology

# Study design

## Design

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|---|---|
| Study type: | Observational invasive |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Treatment |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 06-10-2010 |
| Enrollment: | 4 |
| Type: | Actual |

## Medical products/devices used

| | |
|---|---|
| Product type: | Medicine |
| Brand name: | nvt |
| Generic name: | Diflunisal |
| Registration: | Yes - NL outside intended use |
| Product type: | Medicine |
| Brand name: | nvt |
| Generic name: | N-acetylcysteine |
| Registration: | Yes - NL outside intended use |

# Ethics review

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|---|---|
| Approved WMO Date: | 03-09-2010 |
| Application type: | First submission |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |
| Approved WMO Date: | 10-09-2010 |
| Application type: | First submission |
| Review commission: | BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen) |

# Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

| Register | ID |
|---|---|
| EudraCT | EUCTR2010-022225-14-NL |
| CCMO | NL33554.056.10 |