

# Therapeutic implications of oral hypoglycaemic agents on the enteroinsular axis in type 2 diabetes

**Submission date**

26/09/2007

**Recruitment status**

No longer recruiting

**Registration date**

28/11/2008

**Overall study status**

Completed

**Last Edited**

25/09/2013

**Condition category**

Nutritional, Metabolic, Endocrine

☐ Prospectively registered

☐ Protocol

☐ Statistical analysis plan

☒ Results

☐ Individual participant data

**Plain English summary of protocol**

Not provided at time of registration

## Contact information

**Type(s)**

Scientific

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

## Study information

### Scientific Title

### Study objectives

Metformin inhibits dipeptidyl peptidase IV (DPPIV) degradation and increases physiological effects of glucagon-like peptide-1 (GLP-1).

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Health and Personal Social Services (HPSS) Research Ethics Committee 3, approved on 29th November 2005 (ref: HPSSREC 05/NIR03/181)

### Study design

Randomised cross-over controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Not specified

### Study type(s)

Treatment

### Participant information sheet

### Health condition(s) or problem(s) studied

Type 2 diabetes

### Interventions

Drugs/placebo administered in Study A and B:

A/B 1: one placebo tablet (oral) stat dose

A/B 2: 1 g metformin (oral) stat dose

A/B 3: 120 mg nateglinide (oral) stat dose

In Study A and B all subjects received the two drugs and placebo, one at a time in different orders as single doses, at each visit one week apart. The subjects were given a standard mixed meal. Study B was extended with subjects returning; this time they were kept fasting. In Study A

subjects were not on any oral hypoglycaemic agents. In Study B if any of the subjects were on an oral hypoglycaemic agent this was stopped for a 3-week washout period prior to starting the study.

In Study C and D the subjects received all three combinations below, one combination as a single dose at a time, one week apart:

Cross-over combinations for study C:

C1: placebo (oral) and 1.5 nmol/kg body weight GLP-1 subcutaneous (sc) stat dose

C2: 120 mg nateglinide (oral) and 1.5 nmol/kg body weight GLP-1 sc stat dose

C3: 120 mg nateglinide (oral) and 1 ml normal saline sc stat dose

Cross-over combinations for Study D:

D1: placebo (oral) and 1.5 nmol/kg body weight GLP-1 sc stat dose

D2: 1 g metformin (oral) and 1.5 nmol/kg body weight GLP-1 sc stat dose

D3: 1 g metformin (oral) and 1 ml normal saline sc stat dose

## **Intervention Type**

Drug

## **Phase**

Not Specified

## **Drug/device/biological/vaccine name(s)**

Metformin, nateglinide, glucagon-like peptide-1 (GLP-1)

## **Primary outcome measure**

Blood samples were collected from the participants at -5, 0, 30, 60, 120, 180 and 240 minutes for the measurements of the following:

1. Glucose
2. Insulin
3. C-peptide
4. DPPIV activity
5. GLP-1

## **Secondary outcome measures**

Serum metformin levels, measured by high performance liquid chromatography on blood samples collected at 0, 60, 120 and 240 minutes.

## **Overall study start date**

03/08/2005

## **Completion date**

01/08/2007

# **Eligibility**

## **Key inclusion criteria**

1. Both males and females, aged greater than 18 years
2. Type 2 diabetes controlled by diet or a single oral hypoglycaemic agent
3. HbA1c less than 7.5%
4. No significant liver, cardiac or renal problems (creatinine greater than 150 mmol/l)

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

40

**Key exclusion criteria**

Type 2 diabetes on two or more hypoglycaemic agents or requiring insulin.

**Date of first enrolment**

03/08/2005

**Date of final enrolment**

01/08/2007

**Locations****Countries of recruitment**

Northern Ireland

United Kingdom

**Study participating centre**

11 Village Green

Northern Ireland

United Kingdom

BT39 0UD

**Sponsor information**

**Organisation**

Royal Victoria Hospital (UK)

**Sponsor details**

274 Grosvenor Road,  
Belfast  
Northern Ireland  
United Kingdom  
BT12 6BA

**Sponsor type**

Other

**Website**

<http://www.belfasttrust.hscni.net/hospitals/RVHIntro.htm>

**ROR**

<https://ror.org/03rq50d77>

**Funder(s)****Funder type**

Government

**Funder Name**

Northern Ireland Health and Social Services Central Services Agency (UK) - Research and Development Fellowship (ref: EAT/2955/04)

**Results and Publications****Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/06/2009		Yes	No

<a href="#">Results article</a>	results	01/01/2011	Yes	No
<a href="#">Results article</a>	results	01/03/2011	Yes	No