ISRCTN37245053 https://doi.org/10.1186/ISRCTN37245053

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
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Joy Cuthbertson

Contact details
11 Village Green
Doagh
Ballyclare
Northern Ireland
United Kingdom
BT39 0UD
+44 (0)77614 01203
joycuthbertson@msn.com

Additional identifiers

Protocol serial number
RGHT000140

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
Ramdomised cross-over controlled trial

Primary study design
Interventional

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s))
Serum metformin levels, measured by high performance liquid chromatography on blood samples collected at 0, 60, 120 and 240 minutes.

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
United Kingdom

Northern Ireland

Study participating centre
11 Village Green
Northern Ireland
United Kingdom
BT39 0UD

Sponsor information

Organisation
Royal Victoria Hospital (UK)

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

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?
Results article	results	01/06/2009		Yes	No
Results article	results	01/01/2011		Yes	No
Results article	results	01/03/2011		Yes	No