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Understanding individual variation in treatment response in type 2 diabetes

Submission date	Recruitment status	[ ] Prospectively registered
12/06/2013	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/06/2013	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
20/08/2019	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT01847144

Protocol serial number
14154

Study information

Scientific Title

MASTERMIND: Understanding individual variation in treatment response in type 2 diabetes

Acronym
DRN 788 (MASTERMIND)

Study objectives
Response to treatment in type 2 diabetes is highly variable. The same medicine may have little effect on one person but a huge effect on another. Understanding mechanisms of altered response to treatment could aid treatment selection and assist the design of new medications with lower non- response rates.
This study will examine the physiological mechanisms and potential clinical/biomarker predictors of altered response to sulphonylurea and DPP-IV inhibitor glucose lowering medication and answer fundamental methodological questions for the future study of variation in treatment response in type 2 diabetes.
Participants will withdraw sulphonylurea therapy for up to 4 weeks with assessment of baseline characteristics and glycaemic response. Participants will then enter an optional extension where they receive sulphonylurea or DPP-IV inhibitor therapy in crossover fashion.

Ethics approval required
Old ethics approval format

Ethics approval(s)
12SW0346

Study design
Both; Interventional; Design type: Treatment, Cohort study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Diabetes Research Network; Subtopic: Type 2; Disease: Diabetic Control

Interventions
Gliclazide 80mg OD, Gliclazide 80mg OD; Sitagliptin 100mg OD, Sitagliptin 100mg OD; Study Entry : Registration only

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Gliclazide, sitagliptin

Primary outcome(s)

Understanding mechanisms of individual response to glucose lowering therapies in type 2 diabetes; Timepoint(s): End of study

Key secondary outcome(s))
Not provided at time of registration

Completion date
31/10/2014

Eligibility

Key inclusion criteria
1. Age between 19 and 79 years
2. Clinical diagnosis of Type 2 Diabetes
3. Currently treated with sulphonylurea tablets
4. No change in diabetes treatment (new treatments or dose change) within last 3 months
5. Last HbA1c (taken within last 12 months) of =42 mmol/mol and =75 mmol/mol (6-9%)
6. Able and willing to monitor home blood glucose
7. Able and willing to give informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Current treatment includes: insulin, GLP-1 agonists, DPP-IV inhibitors, glinides, Renal impairment (eGFR <30 ml/min/1.73m2)
2. Active infection (any infection requiring antibiotics at present)
3. Recent (within 3 months) surgery or planned surgery
4. Cardiovascular disease (angina, myocardial infarction, stroke, transient ischemic episode) occurring within the previous 3 months
5. Previous history of pancreatitis
6. Pregnant, breastfeeding or planning a pregnancy over the study period
7. Unable/unwilling to monitor home blood glucose

Date of first enrolment
18/04/2013

Date of final enrolment
31/10/2014

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal Devon and Exeter Hospital
Exeter
United Kingdom
EX2 5DW

Sponsor information

Organisation
Royal Devon and Exeter NHS Foundation Trust (UK)

ROR
https://ror.org/03085z545

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration