

# Understanding individual variation in treatment response in type 2 diabetes

<b>Submission date</b> 12/06/2013	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 12/06/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 20/08/2019	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Ms Catherine Angwin

**Contact details**  
Royal Devon and Exeter Hospital  
Barrack Road  
Exeter  
United Kingdom  
EX2 5DW  
-  
C.Angwin@exeter.ac.uk

## 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  $\leq 42$  mmol/mol and  $\leq 75$  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/1.73m<sup>2</sup>)
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