



## Thames Valley Diabetes Local Research Network

### Study Update

May 2010

#### **Studies currently recruiting**

The following is a list of UKCRN Portfolio studies currently recruiting in participating sites within the Thames Valley Diabetes Local Research Network (TV DLRN). Recruitment to these studies will, in the main, be via hospital clinics or GP practices. Although, from time-to-time, there will be studies where potential participants can self-refer. For further details on any of the studies listed, please contact your local TV DLRN Research Nurse (see page 7 for contact details).

#### **Adolescent Type 1 Diabetes Intervention Trial**

Short title: AdDIT  
DRN Portfolio Reference: DRN068  
Principal Investigators: Dr A Dutta, Dr J Edge, Dr N Mann  
Local participating sites: Oxford Children's Hospital, Royal Berkshire Hospital, Stoke Mandeville Hospital

Intervention trial looking at the effect of angiotensin converting enzyme (ACE) inhibitors and statins in adolescents with Type 1 diabetes and high albumin excretion.

#### **After Diagnosis Diabetes Research Support System**

DRN Portfolio Reference: DRN094  
Short title: ADDRESS  
Principal Investigators: Dr S Chandran, Dr J Edge, Dr I Gallen, Dr V Patel, Dr S Sankar, Dr Hugh Simpson  
Local participating sites: Berkshire, Buckinghamshire, Coventry, Oxfordshire, Milton Keynes and Warwickshire

Register set up to identify children (age 5 and above) and adults newly diagnosed with Type 1 diabetes who consent to their details being held on a database for future contact regarding trials of new treatments or other diabetes studies.

## **ALTITUDE**

DRN Portfolio Reference: DRN344

Principal Investigators: Dr P O'Hare, Dr I Gallen

Local participating sites: Hospital of St. Cross Rugby, Wycombe Hospital

To determine whether the study drug, when added to conventional treatment, delays the occurrence of cardiovascular and renal events in patients with Type 2 diabetes.

## **A Study of Cardiovascular Events in Diabetes**

Short title: ASCEND

DRN Portfolio Reference: DRN023

Local participating sites: Berkshire, Buckinghamshire, Coventry, Hampshire and Isle of Wight, Oxfordshire, Milton Keynes and Warwickshire

A randomised 2x2 factorial study of aspirin versus placebo, and omega-3 fatty acid supplementation versus placebo, for primary prevention of cardiovascular events in people with diabetes.

## **ATLAS2 ACS**

CCRN Portfolio Reference: CCRN013

Principal Investigators: Dr J Glover, Dr N Qureshi

Local participating sites: Basingstoke and North Hampshire Hospital, Warwick Hospital

A randomised, double-blind, placebo-controlled, event-driven multi-centre study to evaluate the efficacy and safety of rivaroxaban in subjects with a recent acute coronary syndrome.

## **Child and Adolescent Structured Competencies Approach to Diabetes Education**

Short title: CASCADE

Principal Investigators: Dr J Burcell, Dr A Dutta, Dr Z Huma, Dr M Russell-Taylor

Local participating sites: Milton Keynes Hospital, Stoke Mandeville Hospital, Wexham Park Hospital, Wycombe Hospital

Maximising engagement, motivation and long-term change in a structured intensive education programme in diabetes for children, young people and their families.

## **Co-Creating Health Initiative**

Short title: CCHi

Local participating sites: Coventry PCT, George Eliot Hospital, Hampshire and Isle of Wight PCT, St Mary's Hospital Isle of Wight, University Hospitals Coventry and Warwick, Warwickshire PCT

The evaluation of the Health Foundation's Co-Creating Health Initiative.

## **D3**

Short title: D3

DRN Portfolio Reference: DRN331

Principal Investigators: Dr M Cummings, Dr I Gallen

Local participating sites: Queen Alexandra Hospital Portsmouth, Wycombe Hospital

Comparing the efficacy of once weekly exenatide versus once or twice daily insulin detemir in patients with Type 2 diabetes.

### **DRN147**

DRN Portfolio Reference: DRN147

Principal Investigator: Dr C Byrne

Local participating site: Southampton General Hospital

Dynamic modelling of the effect of physical activity on capillary blood glucose concentration.

### **DRN306**

DRN Portfolio Reference: DRN306

Principal Investigator: Dr M Cummings

Local participating site: Queen Alexandra Hospital Portsmouth

Assessing the safety and tolerability of study drug versus placebo as an add-on regimen over four months in patients with Type 2 diabetes pre-treated and continuing on a stable dose of metformin.

### **DRN310**

DRN Portfolio Reference: DRN310

Principal Investigator: Prof D Matthews

Local participating site: Churchill Hospital Oxford

A randomised trial evaluating the safety and efficacy of a SGLT2 inhibitor on lowering blood glucose and weight loss in adult patients with Type 2 diabetes.

### **DRN357**

DRN Portfolio Reference: DRN357

Principal Investigators: Dr T Gooding, Prof S Kumar, Dr P O'Hare

Local participating sites: Atherstone Surgery, Hospital of St Cross Rugby, University Hospitals Coventry and Warwick

Trial to confirm the efficacy of study drug once daily + metformin  $\pm$  DPP-4 inhibitor in controlling glycaemia with respect to change from baseline in HbA1c after 26 weeks of treatment.

### **DRN358**

DRN Portfolio Reference: DRN358

Principal Investigator: Dr M Cummings, Dr P Saravanan

Local participating site: George Eliot Hospital, Queen Alexandra Hospital Portsmouth

To confirm the efficacy of study drug three times weekly + metformin  $\pm$  DPP-4 inhibitor in controlling glycaemia with respect to change from baseline in HbA1c after 26 weeks of treatment.

### **Delivering Early Care in Diabetes Evaluation**

Short title: DECIDE

Principal Investigator: Dr N Trevelyan

Local participating site: Southampton General Hospital

A randomised controlled trial to assess hospital versus home management at diagnosis in childhood diabetes.

### **Diabetes, Genes, Autoimmunity and Prevention**

Short title: D-GAP

DRN Portfolio Reference: DRN231

Principal Investigator: Dr J Edge

Local participating site: Oxford Children's Hospital

Observational study looking at the relationship between genes, the immune system and Type 1 diabetes. Recruiting siblings of children diagnosed with Type 1 diabetes under the age of 16 and newly diagnosed children and adults within three months of diagnosis.

### **Diabetes Treatment Satisfaction Questionnaire**

Short title: DTSQ

DRN Portfolio Reference: DRN072

Local participating sites: John Radcliffe Hospital, Milton Keynes Hospital, Queen Alexandra Hospital Portsmouth, Stoke Mandeville Hospital, Wycombe Hospital

Assessing and improving inpatient diabetes treatment satisfaction in different ethnic groups in the UK.

### **Evaluation of Intermediate Care Clinics for Diabetes**

Short title: ICCD

DRN Portfolio Reference: DRN031

Principal Investigators: Dr P O'Hare, Dr P Saravanan

Local participating sites: George Eliot Hospital/Warwickshire PCT, University Hospitals Coventry and Warwick/Coventry PCT

Evaluation of intermediate care clinics (ICC) in the management of Type 2 diabetes.

### **Fear of Hypoglycaemia in Childhood Diabetes**

Short title: Hypo

DRN Portfolio Reference: DRN213

Principal Investigators: Dr J Davies, Dr M Kershaw, Dr K Matyka

Local participating sites: George Eliot Hospital, University Hospitals Coventry and Warwick

Fear of hypoglycaemia in childhood diabetes.

### **Future Revascularisation Evaluation in Patients with Diabetes Mellitus**

Short title: FREEDOM

DRN Portfolio Reference: DRN177

Principal Investigator: Dr M Been

Local participating site: University Hospitals Coventry and Warwick

Future revascularisation evaluation in patients with diabetes: optimal management of multivessel disease.

## **HPS2-THRIVE**

Short title: HPS2-THRIVE  
Principal Investigators: Dr J Armitage, Dr M Been, Dr P O'Hare, Dr P Kalra, Dr S Price, Dr W Orr, Dr C Shearman  
Local participating sites: Clinical Trial Service Unit Oxford, Hospital of St Cross Rugby, Royal Berkshire Hospital, St. Mary's Hospital Portsmouth, Southampton General Hospital, University Hospitals Coventry and Warwick, Wycombe Hospital

Treatment of HDL to reduce the incidence of vascular events: a randomised trial of the long-term clinical effects of raising HDL cholesterol with extended release niacin/lanopiprant.

## **Islet Cell Transplant Outcomes**

DRN Portfolio Reference: DRN115  
Principal Investigator: Dr P Johnson  
Local participating site: Churchill Hospital Oxford  
Establishment of optimised biomedical and psychosocial outcome measures following islet cell transplantation.

## **KICK-OFF**

DRN Portfolio Reference: DRN191  
Principal Investigator: Dr J Edge  
Local participating site: Oxford Children's Hospital  
A multi-centre, randomised controlled trial comparing intensive structured education with standard education in 11-16 year olds on intensive insulin therapy.

## **LanScape**

DRN Portfolio Reference: DRN220  
Principal Investigators: Dr A Baksi, Dr I Gallen, Dr P Saravanan  
Local participating sites: George Eliot Hospital, St Mary's Hospital Isle of Wight, Wycombe Hospital  
A study to compare a basal plus one insulin regimen with a biphasic insulin regimen in controlling HbA1c in Type 2 diabetes.

## **Nephropathy Family Study**

Short title: NFS  
DRN Portfolio Reference: DRN085  
Principal Investigators: Dr A Dutta, Dr J Edge, Dr N Mann  
Local participating sites: Horton Hospital Banbury, Oxford Children's Hospital, Stoke Mandeville Hospital, Royal Berkshire Hospital  
Genetic analysis of risk factors for the development of diabetic complications.

### **Partial Lypodystrophy – Characterisation of Fat Metabolism**

DRN Portfolio Reference: DRN382  
Principal Investigator: Dr S Sulliman  
Local participating site: Churchill Hospital Oxford

Identification of genetic and physiological factors resulting in partial lypodystrophy, and characterisation of cardiac and skeletal muscle structure and blood flow in these subjects.

### **Physical Activity in Children**

DRN Portfolio Reference: DRN103  
Principal Investigator: Dr K Matyka  
Local participating site: University Hospitals Coventry and Warwick

A study looking at the role of reduced physical fitness in cardiovascular disease risk in South Asian children.

### **SIRS**

DRN Portfolio Reference: DRN079  
Principal Investigators: Prof S Kumar, Dr P Latham, Dr J Poulton  
Local participating sites: Churchill Hospital Oxford, Milton Keynes Hospital, University Hospitals Coventry and Warwick

An international, multi-centre study of the genetics of severe insulin resistance.

### **TRA2P-TIMI50**

SRN Portfolio Reference: SRN007  
Principal Investigator: Prof R Wilcox  
Local participating site: University Hospitals Coventry and Warwick

A multi-centre, randomised, double-blind, placebo-controlled study to evaluate the safety and efficacy of SCH 530348 in addition to standard of care in subjects with a history of atherosclerotic disease.

### **Transient Neonatal Diabetes**

DRN Portfolio Reference: DRN407  
Principal Investigators: Dr K Temple, Dr J Thwaites  
Local participating sites: Portsmouth, Southampton  
Clinical and molecular studies of 6q24 transient neonatal diabetes.

### **Young Adult Onset Diabetes**

Short title: YDX  
DRN Portfolio Reference: DRN076  
Principal Investigators: Dr K Owen, Dr H Simpson  
Local participating sites: Churchill Hospital Oxford/Oxfordshire PCT, Royal Berkshire Hospital  
Characteristics of people diagnosed with diabetes aged 45 years or younger: a cross sectional study and incidence study.

## Studies currently in set-up

A number of studies are currently in the process of being set up. Details of these studies will be included as and when all necessary approvals have been given for recruitment to commence.

## Studies closed to recruitment

Details of studies will be removed from this update once recruitment has ended.

## Further information

For further information on any of the above studies and trials recruiting in your area, please contact your local Research Nurse:

<i>Area</i>	<i>Research Nurse</i>	<i>Telephone Number</i>	<i>Email</i>
Berkshire	Julie Sutton	01183 228929 or 07787 128569	juliesutton@nhs.net
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*The Thames Valley Diabetes Local Research Network operates as part of the NIHR Diabetes Research Network in England. It is part of the National Institute for Health Research and forms part of the UK Clinical Research Network. The Networks support and deliver high quality clinical research studies.*

