



Thames Valley Diabetes Local Research Network

Study Update

April 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

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.

BI 1245.33

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.

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.

DRN129

DRN Portfolio Reference: DRN129
Principal Investigator: Dr A Anwar
Local participating site: University Hospitals Coventry and Warwick
A phase 3 trial to evaluate the effectiveness of fragmin compared to placebo on the healing of chronic foot ulcers in diabetic patients with peripheral arterial occlusive disease (PAOD).

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.

DRN357

DRN Portfolio Reference: DRN357
Principal Investigators: Prof S Kumar, Dr P O'Hare
Local participating sites: 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 P Saravanan
Local participating site: George Eliot Hospital
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.

FACTS

Short title: FACTS
DRN Portfolio Reference: DRN067
Local participating sites: George Eliot Hospital, St Mary's Hospital Portsmouth, University Hospitals Coventry and Warwick
A randomised controlled trial to examine whether enhanced family communication improves glycaemic control in adolescents with Type 1 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/laropiprant.

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 Lipodystrophy - 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 lipodystrophy, 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.

