



RESEARCH UPDATE

PRIORITY STUDY

DRN514 - The Vildagliptin Study This is a single-centre, double-blind, randomised, placebo-controlled, parallel-group study to assess the effect of 24 weeks of treatment with vildagliptin on insulin sensitivity and its underlying mechanisms in patients with type 2 diabetes treated with metformin. Eligible patients are referred to the new, high-tech purpose built research facility at the Campus for Ageing and Vitality at the Newcastle Northern General Hospital site where they will receive numerous tests over 24 weeks and 12 visits. This is a commercial study with primary care identifying patients for referral only. Patients are reimbursed for their time and involvement as well as meeting other patients in the same study during study meetings. **Open for recruitment NOW in NTW.**

This issue includes:

- [Studies currently open](#)
- [Studies opening soon](#)
- [Studies closed](#)

For more information about any of the studies included in this booklet please contact the PCRN N&Y office on 01642 615600 or email: enquiries@nyren.co.uk

Studies currently open

SCIMITAR - A Smoking Cessation Intervention for severe Mental Ill Health Trial (SCIMITAR). A pilot study and definitive randomised evaluation of a bespoke smoking cessation service. Various smoking cessation drugs and services are available and are targeted at the general public. However, people with mental health problems may require different strategies and greater support to help them quit smoking. The aim of this study is to evaluate a 'bespoke smoking cessation' (BSC) service specifically tailored to individual patients with severe mental illness. **Open to recruitment in Hull and York.** (NIHR ID: 9690)

DRN 421: LEADER - Liraglutide Effect and Action in Diabetes: Evaluation of Cardiovascular Outcome Results A long-term multi-centre, international, randomised double-blind, placebo-controlled trial to determine liraglutide effects on cardiovascular Events. This commercial (Novo Nordisk) interventional study is co-adopted by the PCRN and is **open in Hull and East Yorkshire.** (NIHR ID: 7869)

Studies opening soon

KCS - Keeping children safe at home This is a large, multi-site observational case controlled study investigating how to best keep children under 4 years old safe at home (from burns, falls and poisoning). Cases are recruited through A&E units at the Queen Elizabeth hospital in Gateshead and the Royal Victoria Infirmary in Newcastle whilst controls will be matched by GP practice to the case. KCS is **coming to Newcastle and Gateshead** from April 2011 and running for 3 years (until 31 August 2013) - and will involve 15,176 accruals nationally. (NIHR ID: 7037)

Studies open continued

PODCAST - Prevention Of Decline in Cognition After Stroke Trial This collaborative, international, randomised, parallel-group, controlled trial aims to determine if intensive BP and lipid lowering to near normal levels after stroke will prevent cognitive decline compared to present moderate lowering treatment.

5000 patients will be enrolled 3-7 months after stroke and treatment will be given for up to 8 years. The primary outcome is Addenbrooks Cognitive Examination (ACE, which includes MMSE) and will be determined during and at end of trial by observers blinded to treatment. Initially, a start-up phase, funded jointly by The Stroke Association and Alzheimer's Society, in 600 patients in the UK will test safety, feasibility and tolerability.

This study will be **recruiting from NTW** soon and will include North Tyneside General Hospital, Hexham and Wansbeck Hospitals in Northumberland, the RVI in Newcastle and South Tyneside General Hospital in South Tyneside.

(NIHR ID: 7847)

Study closed

ASCEND - A Study of Cardiovascular Events in Diabetes
We would like to extend our thanks to all the practices that participated in the recruitment phase of this study.

Although the study is now closed to recruitment it will continue for several years of follow-up. Results will not be available until around the end of 2016 at the earliest.

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Clinical Trial Coordinators

If you have any queries, are interested in participating in a clinical trial or study mentioned in this newsletter, or would like to know which studies are being carried out in your geographical area please contact a Clinical Trial Coordinator.

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