

## Priority Studies for the Diabetic Research Network

Your assistance is urgently required. **Please read.**

We are looking for practices to identify patients, through data base search and mail out for three studies running across NTW CLRN:

### **GSK Study Niacin Study** Study Run at the Clinical Research Facility, Royal Victoria Infirmary-PI Prof Walker.

This is a NIHR high profile study recruiting until December 2011.

The aim of this study is to evaluate whether the glucose lowering effects of GSK256073 are sustained when administered over a 12 week period to subjects with T2DM who are treated with metformin therapy alone.

This is a 12 week multicentre, two-part, randomised, parallel group, placebo and sitagliptin-controlled study.

#### **Main Inclusion Criteria**

- Clinically diagnosed with Type 2 diabetes
- HbA1c levels  $\geq 7.0\%$  and  $\leq 9.5\%$
- On monotherapy with metformin at time of screening and at a total daily dose greater than or equal to 1000mg for at least 2 months prior to dosing
- Fasting plasma glucose level  $< 13.3\text{mmol/L}$  (240 mg/dl) at screening
- A female subject is able to participate if she is of non-childbearing potential
- A male subject must agree to use one of the contraception methods listed in section 8.1 of protocol
- Overweight with BMI  $\geq 25\text{kg/m}^2$  for non-Asian Indians and  $\geq 24\text{kg/m}^2$  for Asian-Indian, and  $<40\text{kg/m}^2$ .

### **TECOS Study** Study Run at Gateshead Diabetes Centre, Bensham Hospital-PI Dr Weaver.

Recruiting until May 2012.

A Randomized, Placebo Controlled Clinical Trial to Evaluate Cardiovascular Outcomes after Treatment with Sitagliptin in Patients with Type 2 Diabetes Mellitus and Inadequate Glycemic Control on Mono- or Dual Combination Oral Antihyperglycemic therapy.

#### **Main Inclusion Criteria**

- Subject has type 2 diabetes mellitus with HbA1c of  $\geq 6.5\%$  (48 mmol/mol) and  $\leq 8.0\%$  (64 mmol/mol) documented within 3 months prior to enrolment, while receiving:
  - metformin, pioglitazone, or a sulphonylurea as monotherapy or any dual combination continuously without alteration in dose for at least 3 months **OR**
  - a stable dose of insulin ( $\pm 20\%$  of the scheduled total daily insulin dose) either alone or in combination with a stable dose of metformin for at least 3 months
- Patient is  $\geq 50$  years of age with pre-existing vascular disease, defined as having:
  - History of a major clinical manifestation of coronary artery disease
  - Coronary revascularization procedure, or coronary angiography showing at least one stenosis  $\geq 50\%$  in a major vessel.

## EXSCEL Study Study running at Clinical Research Facility- PI Prof Walker.

Recruiting until May 2012.

EXenatide Study of Cardiovascular Event Lowering Trial (EXSCEL).

A Randomized, Placebo Controlled Clinical Trial to Evaluate Cardiovascular Outcomes. After Treatment with Exenatide Once Weekly in Patients with Type 2 Diabetes Mellitus.

### Main Inclusion Criteria

- Patient has type 2 diabetes mellitus
- Patient has an HbA<sub>1c</sub> of  $\geq 7.0\%$  and  $\leq 10.0\%$  on stable doses of up to three (i.e. 0-3) oral AHAs for at least 3 months. Concomitant use of DPP-4 inhibitors is permitted
- Patients with any level of CV risk and meeting all other inclusion criteria may be enrolled. (Recruitment will be constrained; approximately 40% will not have had a prior CV event and 60% will have had a prior CV event)
- History of a major clinical manifestation of coronary artery disease, coronary revascularization procedure, or coronary angiography showing at least one stenosis  $\geq 50\%$  in a major vessel
- Ischaemic cerebrovascular disease
- Atherosclerotic peripheral arterial disease
- Female patients must not be breastfeeding and agree to use an effective method of contraception.



## Contact details

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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 your local Clinical Trial Coordinator.

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*The Primary Care Research Network Northern & Yorkshire is part of the NIHR Clinical Research Network, which supports research to make patients, and the NHS, better*