**Research Information Sheet for Practices**

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| **Study Title** | **FAST - Febuxostat versus Allopurinol Streamlined Trial** |
| **Sponsor** | University of Dundee |
| **Funders** | This is an academically led non-commercial trial that is funded by Menarini International Operations Luxembourg SA |
| **Chief Investigator** | Prof Tom MacDonald, Ninewells Hospital and Medical School |
| **Study design** | A prospective, randomised, open-label, blinded endpoint (PROBE) clinical trial |
| **Primary Study Aim & Objectives** | To compare the cardiovascular (CV) safety profile (in terms of Anti Platelet Trialists’ Collaboration [APTC] events) of febuxostat versus allopurinol when taken for an average of 3 years in patients aged 60 years or older with chronic hyperuricaemia in conditions where urate deposition has already occurred. The secondary study objectives are to evaluate other cardiovascular adverse events for both products. |
| **Practice target & study duration** | Approximately 6 patients per practice dependent on list size. 3-5 years duration for each patient |
| **Recruitment period** | November 2014 to July 2016 (inclusive) |
| **Summary of Eligibility Criteria (refer to Protocol for full criteria)** | * Males & females aged >60 yrs * At least one additional cardiovascular risk factor * Require treatment for chronic hyperuricaemia where urate deposition has already occurred * Have received more than 60 days treatment with allopurinol or more than 2 prescriptions within the previous 6 months * **Exclude**  patients with severe renal impairment, a life threatening co-morbidity, congestive heart failure, a current gout flare up or those who have had an MI or stroke within the previous six months |
| **Core Practice Activities** | * Run a database search in line with the inclusion/ exclusion criteria. * GP to check list of identified patients and remove any inappropriate patients * Mail merge the identified list with the practice-headed patient invitation letter and mail to identified patients ( study team will provide prepaid envelopes and prepaid reply slips ) * Provision of suitable clinic room for patient visits * Provide access to patient records for monitoring visits * Assistance with blood test as appropriate * Reporting of serious adverse events (hospitals admissions / deaths) via an easy-to-use web portal |
| **Patient Involvement** | * Attendance at surgery with Research Nurse for consent, health check, blood test. * If urate level is more than 6 mg/dL, Allopurinol dose increased / titrated until correct level achieved and monitored every 2-3 weeks by Research Nurse. * Patient is randomised to either receive Allopurinol or Febuxostat. * 2 monthly follow up of patient by phone, email, letter or visit by Research Nurse * Annual blood tests with research nurse |
| **Resources provided by the study team** | * Study team will provide each participating practice all resources for the mail out, a study Site File and will update practices with any study amendments for the study duration * Trial specific research nurses with assistance from local CRN research nurses |

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**STUDY FLOW CHART**

Identification of eligible patients via clinical system search. Invitation mail out to appropriate patients. Study team liaise with the practice team re available clinic times

Patient response to study team who arrange screening visit

Patient attends screening visit with research nurse to obtain consent, medical history and blood samples

Allopurinol dose optimised (if required)

posted out to patient

Randomisation by telephone

One week washout period where new medication and gout prophylaxis is posted out to patient

Febuxostat

After 2 weeks blood sample taken to check dose is correct.

Research Nurse contact every 2 months. Blood sample at 12 months to check uric acid levels

Allopurinol

Research Nurse contact with patient every 2 months

Blood sample after 12 months to check uric acid levels