***Study contacts***

|  |  |
| --- | --- |
| **Research Officer: Dr Ben Thompson** **Tel: 01869 289296****E-mail: ben.thompson@phc.ox.ac.uk****Chief Investigator: Professor Richard Hobbs**  | **Primary Care Research Facilitator:** **Mobile:** **Email:** **PCTs : Oxfordshire, Berks E and W, Bucks, Milton Keynes** |

**Research Information Sheet for Practices**

**Practice Based Research Nurses**

|  |  |  |
| --- | --- | --- |
| *C:\Users\dlankester\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.Outlook\RFMN01KP\BARACK black and white logo (3).jpg* | **logo****BARACK D** **Benefits of Aldosterone Receptor** **Antagonism in Chronic Kidney Disease Trial****CSP: 107072** |  |

**The Study**

***Study Title*:** Benefits of Aldosterone Receptor Antagonism in Chronic Kidney Disease Trial

***Aims:*** ***Primary objective:***To determine the effect of aldosterone receptor antagonism on mortality and cardiovascular outcomes (onset or progression of cardiovascular disease) in patients with stage 3b CKD.

***Secondary objectives:***To determine the effect of aldosterone receptor antagonism in patients with stage 3b CKD on:

1. Measures of vascular resistance
2. Left ventricular function
3. Decline in renal function – based upon measurement of eGFR
4. Treatment costs and benefits

***Principal Investigator:*** Professor Richard Hobbs

***Host Institution:*** University of Oxford, Department of Primary Care Health Sciences.

(In collaboration with: Universities of Birmingham, Bristol, Manchester, Nottingham, Southampton)

**Number of patients per practice invited**: Approximately 180 who meet stage 3b CKD criteria

**Number of patients per practice recruited:** Approximately 22

**Number of practices in Thames Valley:** 20

**Total Number of Patients Recruited in Thames Valley:** 440 identified as having CKD stage 3b from their last 2 consecutive recorded blood tests.

***Patient recruitment to the study:*** Commencing summer 2013

***Duration of the follow-up:*** 156 weeks (36 months)

***Funded By:*** NIHR School for Primary Care Research

***Inclusion Criteria (summary):***

* Males and females ≥ 18 years of age.
* Evidence of CKD stage 3b from last 2 recorded blood tests.
* Female patients willing to ensure effective contraception for trial period.
* Able and willing (in recruiting GP’s opinion) to comply with all study requirements.

***Exclusion Criteria (summary):***

* Intolerance to Spironolactone or on any prescription medications known to have harmful interactions with Spironolactone.
* Terminal illness, or other significant medical history deemed unsuitable by GP for this trial.
* Hyperkalaemia; Type 1 diabetes mellitus; Addison’s disease.
* Chronic heart failure; recent myocardial infarction (within 6 months); documented symptomatic hypotension; baseline systolic BP under 100mmHg.
* Recent acute kidney injury or admission for renal failure.
* Alcohol or drug abuse, suspected or known.
* Female patient who is pregnant, lactating or planning pregnancy during course of the trial.

**Practice Involvement in the Study – Summary**

***Eligible practices:*** We are seeking:

* 20 GP practices across the Thames Valley
* Practices where at least one GP will: i) act as study site co-ordinator ii) undergo GCP training, iii) confirm patient eligibility iv) support practice nurse / other GPs delivering the intervention.

***Data collection:*** Baseline and follow-up visits - total of 16 visits over 3 years

***By clinicians / practice****:*

* Search electronic clinical records (eCRs) for potential participants; review screening laboratory results to confirm eligibility.
* Review laboratory results and clinical data throughout study to record: i) continuing suitability ii) any adverse events iii) any participant who meets primary or secondary endpoints.
* Record new cardiovascular conditions or death of participants.
* Give participants questionnaires at specified visits.

***By participants***:

* Daily completion of diary cards.
* Complete 5 questionnaires during study.
* Home BP monitoring for a week at 6 specified study points. (Subgroup will also take pulse wave velocity and ambulatory BP measures.)

***By researchers:***

* Baseline health check information collected at screening visit.
* Collection of primary and secondary endpoint data.
* Review of diary cards and questionnaires at end of participants’ period in the study.
* Review of participants at 5 years.

**Practice Involvement: Details of Process**

|  |
| --- |
| ***Patient identification and invitations:*** * Practices will identify potential participants by conducting automated searches of the practice computer database.
* Patients with stage 3b CKD selected from the electronic clinical record using the MDRD and CKD-EPI formulae.
* Site co-ordinating GP will review the list of identified patients to confirm eligibility for screening.
* Practice will send out invitation letters enclosing a trial Patient Information Sheet (PIS), reply slip and pre-paid envelope.
* Patients interested in taking part will return their reply slip to the local co-ordinating centre.

(NB:Patients not wishing to take part can consent to record review only, for comparative study.)***Screening and appointment booking:*** * Surgery staff will book potential participants for a screening visit.
* During the visit the surgery will obtain: patient consent, baseline measurements / samples.
* Participants will be provided with a patient pack and given advice on diary card completion.

***Randomisation:**** GP will review initial clinical data and laboratory tests to confirm eligibility.
* GP will access Sortition, Oxford Primary Care-Clinical Trials Unit’s randomisation system.
* Participants will be allocated randomly to one of the two trial arms: i) standard care alone ii) standard care plus study treatment – Spironolactone.
* Participants in the treatment arm will need: i) prescriptions for Spironolactone ii) advice on how to take it iii) reminder to complete medication monitoring diary card.

***Subsequent appointments:**** Participants will require specific appointments at designated weeks throughout the study.
* Participant attendance will be weeks: 1, 2, 4, 12, 26 then once every 13 weeks until week 156.
* Surgery health professionals collect clinical data, as specified in the Operations Manual.
* Data, including laboratory results, will be reviewed by the GP following each visit and any participants who reach the endpoint criteria will be identified.
 |

***Potential Benefits for the Practice:***

* Opportunity to develop research in your practice (GCP training available).
* Involvement in a study showing a potential new treatment for patients with CKD.
* Reimbursement of all clinical / admin time.

**Patient Confidentiality**

Participant data will only be accessed upon notification of consent being obtained. Data collected will be securely stored in compliance with all national and local regulations.

**If you wish to take part in the study, what happens next?**

***Please complete the sign-up sheet attached to this RISP and post or fax to:*** Tracey Allen

*(Contact details on sign-up sheet)*

**Thank you for your interest in this study.**

**Please call the Research Officer if you would like to discuss this study further**

******

**Summary of Steps to Follow / Flow Chart**

1. eCR List Search and Invitation

 - Identify potentially eligible patients from computer database.

 - Practice sends out invitation letters enclosing: PIS, reply slip, pre-paid return envelope.

 (Anyone not wishing to participate may give consent for medical notes review only, for comparative study)

2. Screening / Baseline Appointment

 - Patients agreeing to participate are contacted by practice to arrange an appointment.

3. Screening / Baseline Visit

 - Discuss study and obtain informed consent.

 - Perform specified investigations including routine venepuncture.

 - Give study pack to participants to take home; explain home completion of diary cards.

4. Randomisation

 - On receipt of venepuncture results, review full baseline assessment to confirm eligibility.

 - Access Sortition (online database) to randomise participants to one of the two trial arms.

 - Provide prescriptions for those randomised to study treatment.

1. Subsequent Appointments

 - Arrange for weeks: 1, 2, 4, 12, 26 and then once every 13 weeks until week 156.

 - Follow visit outlines in Operations Manual.

 - Review data / test results at visits, identify any participants who reach endpoint criteria.

**