

### 3.14 A DOUBLE BLIND CLINICAL TRIAL TO EXAMINE THE RENAL EFFECTS OF AN ANGIOTENSIN CONVERTING ENZYME INHIBITOR (ENALAPRIL) IN ADULTS WITH CHRONIC KIDNEY DISEASE OF UNCERTAIN AETIOLOGY (CKDu)

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#### **Aim**

The purpose of this study is to examine the renal effects of enalapril versus placebo in adults with CKDu by comparing and evaluating the effect of enalapril to a placebo on

- estimated GFR
- albuminuria
- change in stage of CKDu

#### Secondary objectives

- all cause mortality
- cardiovascular mortality

The cause of CKDu is still unknown. In most forms of proteinuric chronic renal disease, glomerular filtration rate continues to decline even when the initial insult has been removed. Main modalities in patients with CKDu to slow down the progression to chronic renal disease are likely to be through control of blood pressure and proteinuria. Angiotensin converting enzyme inhibitors (ACEI) have been shown to be effective in retarding the progress of some forms of proteinuric kidney disease. The effect of ACEI on the progression of CKDu is unknown. If ACEI is found to be effective in retarding the progress of CKDu it will be a cost effective secondary prevention intervention for this major public health problem.

## **METHOD**

The proposed study would be a randomized, double blind clinical trial in which the renal effects of enalapril will be compared to a placebo. Study will be conducted in the Anuradhapura General Hospital. A total of 400 men and women in Grade 1, 2, 3 and 4 stages of CKDu with no exclusion criteria will be enrolled for the study from among those who participated in the epidemiological study from the Anuradhapura district. In order to be eligible, participants must satisfy the case definition of CKDu as defined in the National Research proposal addressing CKD. Participants in Grade 1, 2 and 3 CKDu without any exclusion criteria will be identified based on the epidemiological study data and invited to participate in the study. Those who satisfy the inclusion criteria will be recruited to the study. Those who are already on an ACEI will be allowed to continue and will not be included in the study but will be analysed separately.

Those recruited will be randomized so that half in each of the three groups will receive enalapril (2.5-20 mg/day) and the other half will receive the placebo. The placebo group will also receive a thiazide diuretic (12.5-25 mg/day), if the diastolic blood pressure remains  $\geq 80$  mm Hg after 1 month, atenolol (25-100 mg/day) and other antihypertensives will be added if necessary, at subsequent visits.

Data collected during the baseline visit and the 12 follow up visits will be analyzed to test the change in proteinuria and estimated glomerular filtration rate, in participants receiving enalapril and compared to participants receiving the placebo.

### **Progress**

Recruitment began in July 2011 and concluded in January 2012. Continuation phase is expected to go on until January 2013. Round about 300 participants are now being followed up.