



Title	Aspirin To Target Arterial events in Chronic Kidney Disease
Acronym	ATTACK
Chief Investigators	Prof Hugh Gallagher Prof Paul Roderick
Objectives	To test the hypothesis that the addition of 75mg aspirin once daily to usual care reduces the risk of major vascular events in patients with chronic kidney disease (CKD) who do not have pre-existing cardiovascular disease (CVD)
Trial Configuration	Open label, multi-centre study
Setting	Primary care
Sample size estimate	25,210 patients (12,605 per arm). A total of 1,827 major vascular events overall are required.
Number of participants	We expect to invite approximately 198,000 patients in order to recruit the 25,210 required. Of these 12,605 will be randomised to aspirin 75 mg once daily and 12,605 to no additional treatment (with avoidance of aspirin).
Eligibility criteria	<u>Inclusion Criteria</u> <ol style="list-style-type: none"> 1. Males and females aged 18 years and over at the date of screening 2. Subjects with diagnosed CKD: <ul style="list-style-type: none"> • decreased estimated glomerular filtration rate [eGFR] for at least 90 days (defined as $eGFR < 60 \text{ mL/min/1.73m}^2$), and/or • albuminuria or proteinuria for at least 90 days (defined as urine albumin:creatinine ratio [ACR] $\geq 3 \text{ mg/mmol}$, and/or urine protein:creatinine ratio [PCR] $\geq 15 \text{ mg/mmol}$, and/or +protein or greater on reagent strip [and in all cases where the most recent qualifying result is $ACR \geq 3 \text{ mg/mmol}$]) 3. Subjects who are willing to give permission for their paper and electronic medical records to be accessed by trial investigators 4. Subjects who are willing to be contacted and interviewed by trial investigators 5. Subjects who can communicate well with the investigator or designee, understand the requirements of the study and understand and sign the written informed consent

	<p><u>Exclusion Criteria</u></p> <ol style="list-style-type: none"> 1. Subjects with CKD GFR category 5 2. Subjects with pre-existing cardiovascular disease (angina, MI, stroke, TIA, significant peripheral vascular disease, coronary or peripheral revascularisation for atherosclerotic disease) 3. Subjects with a pre-existing condition associated with increased risk of bleeding other than CKD 4. Subjects taking over-the-counter aspirin continuously 5. Subjects currently prescribed anticoagulants or antiplatelet agent 6. Subjects who are currently and regularly taking other drugs with a potentially serious interaction with low-dose aspirin 7. Subjects with a known allergy to aspirin or definite previous clinically important adverse reaction 8. Subjects with poorly controlled hypertension, defined as average of three readings at screening visit of systolic BP ≥ 180mm Hg and/or diastolic BP ≥ 105mm Hg 9. Subjects with anaemia: Hb < 90g/L; or Hb < 100g/L with MCV (MCV) ≤ 75 fL 10. Subjects who are pregnant or likely to become pregnant during the study period 11. Subjects with malignancy that is life-threatening or likely to limit prognosis, other life-threatening co-morbidity, or terminal illness 12. Subjects whose behaviour or lifestyle would render them less likely to comply with study medication 13. Subjects in prison 14. Subjects currently participating in another interventional clinical trial or who have taken part in a trial in the last three months
Description of interventions	Suitable participants will be randomised to receive: 75mg non-enteric coated aspirin once daily in addition to their usual medication; or no additional treatment
Duration of study	The trial will continue until 1,827 major vascular events have occurred: this is anticipated 6 years after the recruitment start date, or 2.5 years following the recruitment end date
Randomisation and blinding	Eligible participants, based on results of blood tests taken at screening, will be randomised (open label randomisation) 1:1 to GP prescription of aspirin vs. no prescription, stratified by age, diabetes and CKD severity
Primary outcome measures	Time to first major vascular event from the date of randomisation. A major vascular event is defined as a primary composite outcome of non-fatal myocardial infarction, non-fatal stroke and cardiovascular death (excluding confirmed intracranial haemorrhage).

***For further details, please contact:
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