WHO data registry

Data Category	**Information**
Primary registry and trial identifying number	Australia New Zealand Clinical Trials Registry ACTRN12619001573145p
Date of registration in primary registry	14/11/2019
Secondary identifying numbers	U1111-1267-9602 (UTN) 2019/ETH00200
Source(s) of monetary or material support	The University of Sydney
Primary sponsor	The Western Sydney Local Health District
Secondary sponsor(s)	N/A
Contact for public queries	Dr Rahena Akhter
Contact for scientific queries	Prof Joerg Eberhard
Public title	Treatment of gum disease to reduce cardiovascular risk
Scientific title	Targeting the systemic inflammation associated with periodontitis to reduce risk in patients with coronary artery disease and on statin therapy- a randomized feasibility study
Countries of recruitment	Australia
Health condition(s) or problem(s) studied	Coronary artery disease Periodontitis
Intervention(s)	Participants will be allocated to one of 4 arms: 1) Periodontal treatment 2) Colchicine administration 3) Periodontal treatment + colchicine administration 4) No treatment Periodontal treatment will involve scaling and root planing. This will be performed over 3 separate appointments, beginning at baseline with a 1-2 week interval between appointments. Treatment will be carried out by a registered oral health practitioner at the Westmead Centre for Oral Health. Colchicine will be administered via 0.5mg tablets to be taken by the participants once daily for 8 weeks.
Key inclusion and exclusion criteria	**Medical inclusion criteria:** Have coronary artery disease (acute coronary syndrome/ stable angina and are on statin therapy. ≥ 18 years. **Medical Exclusion criteria:** currently taking or have had antibiotic therapy in the last 3 months. currently pregnant, lactating of planning pregnancy. severe renal impairment: GFR <30. severe hepatic impairment: History of CKD and or alanine aminotransferase >3 upper limit of normal [ULN]). Blood dyscrasias. Taking medications that interact with Colchicine. **Dental inclusion criteria:**

	No subgingival scaling and root planning in the last 6 months. ≥ 15 teeth. Mod-severe periodontitis. **Dental Exclusion criteria:** Received subgingival scaling and root planning in the last 6 months. < 15 teeth Mild periodontitis
Study type	Interventional
Date of first enrolment	23/06/2022
Target sample size	60
Recruitment status	Recruiting
Primary outcome(s)	1) Difference in hsCRP
Key secondary outcomes	1) Difference in lipids and periodontal parameters 2) Feasibility measures (recruitment conversion rate, completion rate, safety and tolerability, trial evaluation)