Effect of Remote Ischaemic Conditioning in ONCology patients undergoing chemotherapy: Background and study design of the ERIC-ONC study

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Background: Improved cancer survivorship paradoxically exposes patients to acute and chronic cardiovascular consequences. Anthracycline chemotherapy regimens continue to play a prominent role in many cancer treatments, but conventional cardioprotection strategies have important haemodynamic or myelosuppressive side effects. Remote ischaemic conditioning (RIC), delivered as intermittent inflations and deflations of a peripheral blood pressure cuff, reduces acute lung injury and cardiac troponin release in elective lung cancer surgery and acute myocardial infarction, respectively. Anthracycline cardiotoxicity and reperfusion injury share final common pathways in cardiomyocytes. The potential for RIC as a novel treatment to reduce sub-clinical cardiomyocyte injury in chemotherapy has never been explored and is currently being investigated in the ERIC-ONC study (clinicaltrials.gov NCT 02471885).

Study Design: The ERIC-ONC trial is a double blind randomised controlled trial. We aim to recruit 128 oncology patients undergoing anthracycline-based chemotherapy treatment, randomised in a 1:1 ratio into two groups (1) sham procedure, or (2) RIC, comprising four 5-minute cycles of upper arm blood pressure cuff inflations and deflations, immediately before each cycle of chemotherapy.

Outcomes: The primary outcome measure, defining cardiac injury, will be high-sensitivity troponin T (hs-TnT) over six cycles chemotherapy and 12-months' follow up. Secondary outcome measures will include clinical, electrical, structural, and biochemical endpoints comprising major adverse cardiovascular clinical events (MACCE), cardiac arrhythmias monitored for 14 days at cycle 5/6, echo global longitudinal strain (GLS), NT-proBNP, mitochondrial DNA, micro RNA, and protein expression at baseline and three months' follow up.

Implication: The ERIC-ONC trial will determine the efficacy of RIC as a non-invasive, non-pharmacological cardioprotection technique in cancer patients undergoing anthracycline-based chemotherapy. This novel clinical trial will further the cardio-oncology care paradigm to prevent today's cancer survivor from becoming tomorrow's cardiac patient.

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