The role of Ischaemic Preconditioning In non-cardiac surgery. A multicenter, randomized controlled trial protocol.

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Argomento: Anestesia generale

Background Remote ischemic preconditioning (RIPC) by brief episodes of ischemia and reperfusion in a remote organ or vascular territory provides protection from injury by myocardial ischemia and reperfusion. Interestingly, propofol seems to inhibit the properties of organ protection of many drugs and strategies including RIPC. To date, despite increasing evidence suggests a cardioprotective beneficial effect of RIPC in cardiac surgery, no clinical trial in non-cardiac surgery setting has been performed.

Objectives The primary endpoint of the study is to document a reduction in postoperative cardiac troponin values in patients receiving RIPC when compared to patients not receiving this cardioprotective strategy. Secondary endpoints will be 30 days cardiac ischemic events, mortality at 30 days, 30-days neurologic events, acute kidney injury, need for ICU, lenght of hospital stay.

Methods The study will be a multicenter, randomized, double blind clinical trial. We plan to enroll 1.100 adults meeting these inclusion criteria: patients undergoing intermediate and high risk non-cardiac surgery; general anesthesia; ongoing or recently suspended antiplatelet therapy. Exclusion criteria: pregnancy; planned locoregional anesthesia; unstable or ongoing angina; recent or ongoing myocardial infarction; peripheral vascular disease; cardiac surgery. General anesthesia will be induced and maintained without the use of propofol. Three cycles of remote ischemic preconditioning will be performed by inflation of a blood-pressure cuff to 200 mm Hg to the upper arm for 5 minutes, followed by 5 min reperfusion with the cuff being deflated, just after the induction of anesthesia. All patients will undergo postoperative serum troponin dosage and ECG.

Expected outcomes We expect a different postoperative cardiac troponin T release in the two groups defined as the occurrence of both an elevation (>14 ng/L) and a change (>85%) of high sensitivity cardiac troponin T values.