Intravenous amino acid therapy for kidney protection in cardiac surgery: a multi-centre randomised blinded placebo controlled clinical trial.

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Argomento: Funzione renale e metabolica in terapia intensiva

Background Cardiac surgery is the second major cause of acute kidney injury (AKI) in critically ill patients. Cardiac-surgery associated AKI is a major healthcare problem which increases morbidity and mortality. Amino-acids may have a role in AKI's management in critically ill patients: a strong biological rationale for their use is well described in literature and it is demonstrated that they also increase renal blood flow and glomerular filtration rate providing nephroprotection.

Objectives We designed a phase III, multicenter RCT to establish whether providing continuous infusion of amino-acids reduces the incidence of AKI in patients undergoing cardiac surgery. If our hypothesis will be confirmed, we will have a low cost and effective strategy to improve outcome in these patients.

Methods The study comprises 2 arms and will be conducted on 3500 patients (1750 in each arm) in multiple sites. Inclusion criteria will be: adult patients; scheduled cardiac surgery; expected to stay in ICU at least one night after surgery. Exclusion criteria: patient currently receiving or scheduled for intermittent or continuous RRT; CKD at least stage IV; kidney transplant; not expected to survive ICU or hospital discharge; severe liver disease (Child-Pugh score >7 points); congenital alteration of amino-acid metabolism; pregnant or breastfeeding; hypersensitivity to the included amino-acids; Patients are randomized to receive either continuous infusion of a balanced mixture of amino-acids in a dose of 2 g/kg-ideal-body-weight/day (to a maximum 100 g/day) from the operating room admission up to either death, start of RRT, ICU discharge or 72 hours after randomization (whichever occurs first), or placebo.

Expected results We expect to assess a 20% reduction in relative risk, corresponding to a 5% absolute risk reduction in AKI incidence in the treatment arm from an estimated baseline AKI rate of 25%. This study received a grant from Italian Ministry-of-Health, Ricerca-Finalizzata 2016, n. RF-2016-02363260.