COGiTATE phase II study: feasibility and safety of targeting an optimal cerebral perfusion pressure as a patient - tailored therapy in severe traumatic brain injury.

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Argomento: Neuroanestesia e neurorianimazione

Background. Monitoring cerebral autoregulation in traumatic brain injury (TBI) patients can indicate an individual cerebral perfusion pressure (CPP) target for which autoregulation is best preserved (Optimal CPP, CPPopt - fig.1). This offers a precision medicine apporach with hypothetical advantage over the current 'one size fits all' strategy. Large retrospective data suggest that managing CPP close to CPPopt has a benefit in outcome. A prospective evaluation of CPPopt guided therapy is needed, but before performing an outcome study it is necessary to assess the feasibility and safety of such a protocol. The primary objective of COGiTATE (CppOpt GuIded Therapy Assessment of Target Effectiveness) is to demonstrate feasibility of individualising CPP at CPPopt in TBI patients, expressed as the percentage of monitoring time for which CPP is within 5 mmHg of regularly updated CPPopt targets during the first 5 days of Intensive Care Unit (ICU) admission. Secondary objectives are to investigate the safety (increases of the Treatment Intensity Level) and physiological effects of this strategy (changes in autoregulation indexes, organ function parameters).

Methods. COGiTATE is a phase II non-blinded, randomised controlled trial currently ongoing in the ICU of 3 tertiary hospitals in Cambridge, Leuven and Maastricht. Severe TBI patients requiring intracranial pressure directed therapy, are enrolled in the first 24 hours after ICU admission and allocated into two groups. In the intervention group the CPP target (CPPopt) is calculated using a (modified) algorithm previously described by Liu X et al. and clinically reviewed 4-hourly. The control group uses a fixed CPP target between 60-70mmHg.

Results. Patient recruitment started in February 2018 and will continue until 60 patients are studied. 32 patients have been recruited so far.

Conclusion. A prospective evaluation of feasibility, safety and physiological implications of autoregulation guided management will give evidence useful for the design of a phase III study.