

A Phase II Clinical Trial to assess the safety of Clonidine in Acute Organophosphate Poisoning

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Objective: To determine the safety of clonidine given as an antidote in adult patients presenting with signs or symptoms of acute organophosphate ingestion. **Methodology:** This study was a dose finding, open-label, multicentre, phase II trial. Forty eight patients with acute organophosphate poisoning were randomized to receive either clonidine or placebo: Four to receive placebo and twelve to receive clonidine at each dose level. The first dose level was an initial loading dose of 0.15 mg followed by an infusion of 0.5 mg of clonidine over 24 hours. The initial loading dose was increased to 0.3 mg, 0.45 and 0.6 mg. in the subsequent dosing levels however the infusion rate remained the same.

Findings: The baseline characteristics of both groups were similar. The trial was stopped after completion of the 3rd dosing level. At the 1st and 2nd dosing level there were no reported adverse events. At the 3rd dosing level 5 patients (42%) developed significant hypotension during clonidine treatment. There were no statistical difference in ventilation rate, pre and post GCS, and mortality rates over all levels. **Conclusions:** Our findings suggest that clonidine is well tolerated at the two lowest dosing levels; higher doses are associated with a high incidence of hypotension requiring intervention. These initial findings support doing further studies to characterize the efficacy profile of clonidine as an alternative antidote