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A randomised study in healthy volunteers to investigate the safety, tolerability and pharmacokinetics of idarucizumab, a specific antidote to dabigatran

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Summary

Idarucizumab, a monoclonal antibody fragment that binds dabigatran with high affinity, is in development as a specific antidote for dabigatran. In this first-in-human, single-rising-dose study, we investigated the pharmacokinetics, safety and tolerability of idarucizumab. Healthy male volunteers aged 18–45 years received between 20 mg and 8 g idarucizumab as a 1-hour intravenous infusion in 10 sequential dose groups, or 1, 2 or 4 g idarucizumab as a 5-minute infusion. Subjects within each dose group were randomised 3:1 to idarucizumab or placebo. A total of 110 randomised subjects received study drug (27 placebo, 83 idarucizumab). Peak and total exposure to idarucizumab increased proportionally with dose. Maximum plasma concentrations were achieved near the end of infusion, followed by a rapid decline, with an initial idarucizumab half-life of 45 minutes. For the 5-minute infusions, this resulted in a reduction of plasma concentrations to less than 5 % of peak within 4 hours. Idarucizumab (in the absence of dabigatran) had no effect on coagulation parameters or endogenous thrombin potential. Overall adverse event (AE) frequency was similar for idarucizumab and placebo, and no relationship with idarucizumab dose was observed. Drug-related AEs (primary endpoint) were rare (occurring in 2 placebo and 3 idarucizumab subjects) and were mostly of mild intensity; none of them resulted in study discontinuation. In conclusion, the pharmacokinetic profile of idarucizumab meets the requirement for rapid peak exposure and rapid elimination, with no effect on pharmacodynamic parameters. Idarucizumab was safe and well tolerated in healthy males.



Clinical trial registration: <http://clinicaltrials.gov/ct2/show/NCT01688830?term=NCT01688830&rank=1> (NCT01688830).

Keywords

Antidote - dabigatran etexilate - idarucizumab - reversal agent - safety

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