

primary studies - published RCT

# A randomised controlled trial of rosuvastatin for the prevention of aminoglycoside-induced kidney toxicity in children with cystic fibrosis.

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#### Study design (if review, criteria of inclusion for studies)

Open label, parallel group, randomised controlled trial

## **Participants**

Children and young people aged 6 to 18 years with CF at 13 paediatric CF treatment centres in the UK.

#### Interventions

Participants were randomised equally to either receive oral rosuvastatin (10 mg once daily) or no intervention (control) throughout clinically indicated treatment with intravenous tobramycin.

## Outcome measures

The primary outcome was the difference between the groups in mean fold-change in urinary Kidney Injury Molecule-1 (KIM-1).

#### Main results

Fifty (rosuvastatin n = 23, control n = 27) participants were recruited between May 2015 and January 2017. Primary outcome data was available for 88% (rosuvastatin n = 20, control n = 24). The estimated mean treatment difference in the geometric mean-fold change of normalised KIM-1 was 1.08 (95% CI 0.87-1.35, p = 0.48). In total there were 12 adverse reactions, all mild, reported by five participants randomised to rosuvastatin, and one serious adverse event in each group. Whilst no protective effect of rosuvastatin was seen, there was a lower than expected level of nephrotoxicity in the cohort. Therefore, we can neither confirm nor refute the hypothesis that rosuvastatin protects against aminoglycoside nephrotoxicity.

## Authors' conclusions

Authors can neither confirm nor refute the hypothesis that rosuvastatin protects against aminoglycoside nephrotoxicity.

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## See also

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#### Keywords

Rosuvastatin; Statins; Anti-Inflammatory Agents - excl Steroids; pharmacological\_intervention; Aminoglycosides; Anti-Bacterial Agents;