Impact of rosuvastatin on progression of atherosclerosis in people with HIV at moderate cardiovascular risk; a multicentre, randomised, double blind, placebo-controlled trial.

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Background:
People with HIV (PWHIV) are at increased risk for cardiovascular disease. This study aimed to determine if PWHIV would benefit from starting statins at a lower threshold than currently recommended in the general population.

Methods:
A double-blinded multicentre, randomised, placebo-controlled trial was performed. Participants were adults with well controlled HIV at moderate cardiovascular risk (Framingham risk score of 10-15%) who were not recommended to be on statin therapy. They were recruited from HIV centres in Australia and Switzerland. Participants were randomised 1:1 to rosuvastatin 20mg oral daily or matched placebo for 96 weeks stratified by site. Detailed assessments including fasting bloods and carotid intima media thickness (CCA-IMT) were performed at baseline, and weeks 48 and 96. The primary outcome was the change from baseline to week 96 in CCA-IMT.

Results:
Participants (n=88) were randomised to rosuvastain (n=44) or placebo (n=40) from July 2013 to August 2016. They were predominantly male (82 (97·6%)); mean age 54 years (SD 6·0). At 96 weeks there was no difference in the change CCA-IMT between the rosuvastatin (mean 0·004mm, SD 0·0036) and placebo (0·0062mm, SD 0·0039) arms (p value =0·684), leading to no difference in CCA-IMT levels between groups at week 96 (rosuvastatin arm, 0·7232mm (SD 0·030); placebo arm 0·7785mm (SD 0·032), p=0·0749).

Adverse events were common (n=146) but mostly mild, grade one or two (131 [89%]) but were more common in the rosuvastatin arm (108 [73·9%]) vs placebo (38 [26·0%]). Participants on rosuvastatin were more likely to cease study medication due to an adverse event (12 [27·2%] vs 2 [5·0%]).

Conclusion:

The prescription of statins to people with HIV at a lower threshold than general population guidelines did not lead to improvements in surrogate markers of cardiovascular disease but was associated with a significant rate of adverse events.

Disclosure of Interest Statement:
Dr Trevillyan has received honoraria from Gilead Health Sciences for speaker responsibilities unrelated to this project. Professor Hoy's institution has received reimbursement for her participation in Advisory Boards for Gilead Sciences, ViiV Healthcare and MSD. Professor Calmy's institution has received unrestricted educational grants from Gilead Health Sciences, ViiV, AbbVie and MSD.