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Efficacy and safety of statin therapy in kidney transplant recipients: a meta-analysis

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Abstract

The present systematic review and meta-analysis aims to evaluate the effiacy and safety of HMG CoA Reductase Inhibitor (statin) therapy among kidney transplant recipients. The primary outcome will be the occurence of major adverse cardiovascular events. Both randomized controlled trials and cohort studies will be held eligilble. Random-effects meta-analysis models will be fitted to provide pool estimates of hazard or risk ratio. The certainty of evidence will be critically assessed following the GRADE approach.

Troubleshooting

1 Objective To determine the efficacy and safety of HMG CoA reductase inhibitor (statin) treatment in kidney transplant recipients.

2 Eligibility criteria The population of the study will consist of kidney transplant recipients. The intervention of interest will be statin administration, given for primary or secondary cardiovascular prevention. The intervention will be compared to placebo or standard care. The primary outcome of interest will be the occurrence of major adverse cardiovascular events (MACE). Secondary efficacy outcomes will include patient survival and kidney allograft survival. Safety endpoints will include the following: hepatotoxicity, rhabdomyolysis, creatine kinase elevation, post-transplant diabetes mellitus, cataract, venous thromboembolic events, hip fracture and cancer. Randomized controlled trials and observational (cohort and case-control) studies will be held eligible. Cross-sectional and descriptive studies, review articles and in vitro studies will be excluded.

3 Literature search Literature search will be performed by systematically searching from inception PubMed, Scopus, Web of Science, CENTRAL (Cochrane Central Register of Controlled Trials) and ClinicalTrials.gov. In addition, Google Scholar will be screened to provide grey literature coverage, while the full reference lists of the included studies will be examined to recognize potential missing articles. No date/language restrictions will be applied.

4 Data extraction The following data will be extracted: year of publication, country, eligibility criteria, sample size, study design, type of statin, percentage of male sex, diabetes mellitus, hypertension, mean age, body mass index, type of immunosuppression (calcineurin inhibitors/mTOR inhibitors) as well as all the necessary information regarding the outcomes of interest.

5 Quality assessment The quality of randomized controlled trials will be assessed with the RoB-2 tool, which takes into account the following domains: randomization, deviations from intended interventions, missing outcome data, measurement of the outcome and selection of the reported results. The risk of bias of the included cohort studies will be evaluated with the ROBINS-I tool, which takes into account the following domains: confounding, selection of participants, classification of interventions, departures from intended interventions, missing data, measurement of outcomes and selection of the reported results.

6 Data analysis Confidence intervals will be set at 95%. Random-effects models will be fitted using the maximum likelihood method for between-study variance estimation. Pool estimates of hazard and risk ratios will be calculated. The inter-study heterogeneity will be quantified by the inconsistency index (I2), while the 95% predictive intervals will be calculated to assess the effects to be expected by future studies. Subgroup analysis is planned based on the following parameters: study design, location, sample size and type

of calcineurin inhibitor. Funnel plots will be constructed and the Egger's test will be performed to assess their asymmetry, if appropriate (>10 studies).

7 Quality of evidence The quality of the existing evidence will be appraised following the GRADE approach. Specifically, evidence will be classified as very low, low, moderate or high by judging the following domains: study limitations, consistency, directness, imprecision and publication bias.