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Safety of red yeast rice supplementation: a systematic review and meta-analysis of randomized controlled trials.

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BACKGROUND: Recently, concerns regarding the safety of red yeast rice (RYR) have been raised after the publication of some case reports claiming toxicity.

PURPOSE: Since the previous meta-analyses on the effects of RYR were mainly focused on its efficacy to improve the lipid profile and other cardiovascular parameters, we carried out a meta-analysis on safety data derived from the available randomized controlled clinical trials (RCTs).

METHODS: Primary outcomes were musculoskeletal disorders (MuD). Secondary outcomes were non-musculoskeletal adverse events (Non-MuD) and serious adverse events (SAE). Subgroups analyses were carried out considering the intervention (RYR alone or in association with other nutraceutical compounds), monacolin K administered daily dose (=3, <3-5 and >5 mg/day), follow-up (>12 or =12 weeks), with statin therapy or statin-intolerance and type of control treatment (placebo or statin treatment).

RESULTS: Data were pooled from 52 RCTs comprising 110 treatment arms, which included 8503 subjects, with 4421 in the RYR arm and 4287 in the control one. Monacolin K administration was not associated with increased risk of MuD (odds ratio [OR]=0.94, 95% confidence interval [CI] 0.53,1.65). (Figure below presents the forest plot comparing the RYR associated risk of MuD in the entire population). Moreover, we found a reduced risk of Non-MuD (OR=0.59, 95%CI 0.50, 0.69) and SAE (OR=0.54, 95%CI 0.46, 0.64) vs. control. Subgroups analyses confirmed the high tolerability profile of RYR. Furthermore, increasing daily doses of monacolin K were negatively associated with increasing risk of Non-MuD (slope: -0.10; 95%CI: -0.17, -0.03; two-tailed p<0.01).

CONCLUSIONS: Based on our data, RYR use as lipid-lowering dietary supplement seems to be overall tolerable and safe in a large population of moderately hypercholesterolaemic subjects.
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