

Steroid treatment is associated with high-risk of adverse events for kidney disease: Study

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Unexpectedly large increase in the risk of serious adverse events, primarily infections among patients with IgA nephropathy and excess protein in their urine



Treatment with pills of the steroid methylprednisolone was associated with an unexpectedly large increase in the risk of serious adverse events, primarily infections among patients with IgA nephropathy and excess protein in their urine. This study was recently conducted by George Institute for Global Health.

Dr. Vivekanand Jha, Executive Director of the George Institute for Global Health, India, and one of the authors associated with the study said, "Up to 30 percent of all people with IgA nephropathy will eventually develop end-stage kidney disease. Decreased kidney function, persistent proteinuria, and hypertension are the strongest risk factors."

Guidelines recommend corticosteroids in patients with IgA nephropathy and persistent proteinuria, and they are widely used in these patients, but the benefits and risks have not been clearly established. In the study, participants with IgA nephropathy and proteinuria were randomly assigned to oral methylprednisolone (n = 136) or placebo (n = 126) for 2 months, with subsequent weaning over 4 to 6 months.

Recruitment was planned in several countries including China and India but after 2.1 years' median follow-up, recruitment was discontinued because of an unexpectedly high rate of serious adverse events (including infections, gastrointestinal, and bone disorders). Serious events occurred in 20 participants (14.7 percent) in the methylprednisolone group vs 4 (3.2 percent) in the placebo group, mostly due to excess serious infections (8.1 percent vs 0), including two deaths. The primary renal outcome (end-stage kidney disease, death due to kidney failure, or a 40 percent decrease in estimated glomerular filtration rate [a measure of substantial loss of kidney function]) occurred in 8 participants (5.9 percent) in the methylprednisolone group vs 20 (15.9 percent) in the placebo group.

Vlado Perkovic of the George Institute for Global Health Sydney and a lead author of the study said, "Although the results were consistent with potential renal benefit, definitive conclusions about treatment benefit cannot be made, owing to early termination of the trial."

Prof. Hong Zhang of Peking University First Hospital, Beijing adds, "A limitation of the study was recruitment was stopped earlier than planned because of excess adverse events and so the power of the study was less than predicted, and both risks and benefits might be overestimated thus."