

# A Randomized Trial of Cyclosporine in Patients with Steroid-Resistant Focal Segmental Glomerulosclerosis

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## Abstract

### Background

A clinical trial of cyclosporine in patients with steroid-resistant focal segmental glomerulosclerosis (FSGS) was conducted. Despite the fact that it is the most common primary glomerulonephritis to progress to renal failure, treatment trials have been very limited.

### Methods

We conducted a randomized controlled trial in 49 cases of steroid-resistant FSGS comparing 26 weeks of cyclosporine treatment plus low-dose prednisone to placebo plus prednisone. All patients were followed for an average of 200 weeks, and the short- and long-term effects on renal function were assessed.

### Results

Seventy percent of the treatment group versus 4% of the placebo group ( $P < 0.001$ ) had a partial or complete remission of their proteinuria by 26 weeks. Relapse occurred in 40% of the remitters by 52 weeks and 60% by week 78, but the remainder stayed in remission to the end of the observation period. Renal function was better preserved in the cyclosporine group. There was a decrease of 50% in baseline creatinine clearance in 25% of the treated group compared with 52% of controls ( $P < 0.05$ ). This was a reduction in risk of 70% (95% CI, 9 to 93) independent of other baseline demographic and laboratory variables.

### Conclusions

These results suggest that cyclosporine is an effective therapeutic agent in the treatment of steroid-resistant cases of FSGS. Although a high relapse rate does occur, a long-term decrease in proteinuria and preservation of filtration function were observed in a significant proportion of treated patients.

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**Keywords:** FSGS, cyclosporine, glomerulonephritis, immunosuppression, nephrotoxicity