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# An open-label randomized controlled trial comparing solo prednisolone therapy vs steroid-sparing agent along with daily doses of prednisolone in achievement of remission among FRNS and SDNS patients

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## Introduction

Approximately 50% of children who present with SSNS will develop FRNS or SDNS. Steroid toxicity is the most dreaded complication when treating children with NS and minimization of steroids has become of utmost importance. The use of steroid-sparing agents (SSA) has led to better control of the disease with the lowest possible cumulative dose of prednisolone. Several studies have been done comparing different SSA and their indications, but no guideline exists as to when the drugs should be started in the treatment of a relapse case in the FRNS/SDNS cohort.

## Objectives

### Primary objective

- To assess the efficacy of early initiation of SSA with a daily dose of prednisolone compared to only prednisolone therapy in achieving remission among patients aged 1-14 years diagnosed with FRNS/SDNS.

### Secondary objective

- To determine the relapse rate in both intervention arms over 6 months.

## Hypothesis

- **Null hypothesis**: Adding steroid-sparing agents with a daily dose of prednisolone does not help in the faster achievement of remission in patients aged 1-14 years diagnosed with FRNS or SDNS.
- **Alternate hypothesis**: Adding steroid-sparing agents with a daily dose of prednisolone before achievement of remission helps in faster achievement of remission among patients aged 1-14 years diagnosed with FRNS or SDNS.

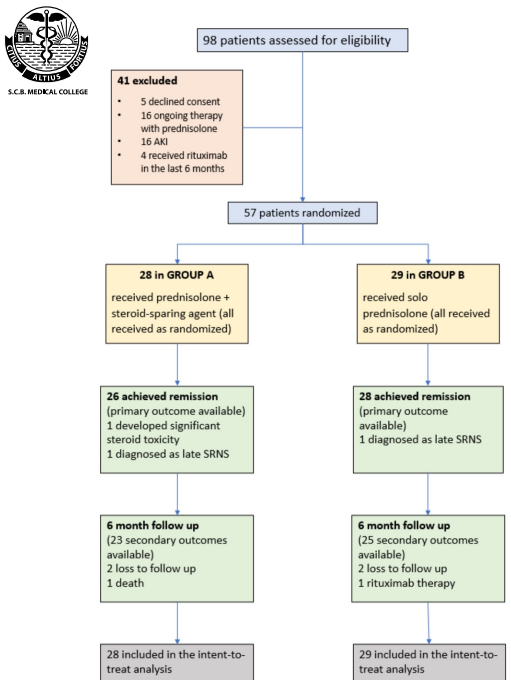


Fig 1. CONSORT diagram of the study

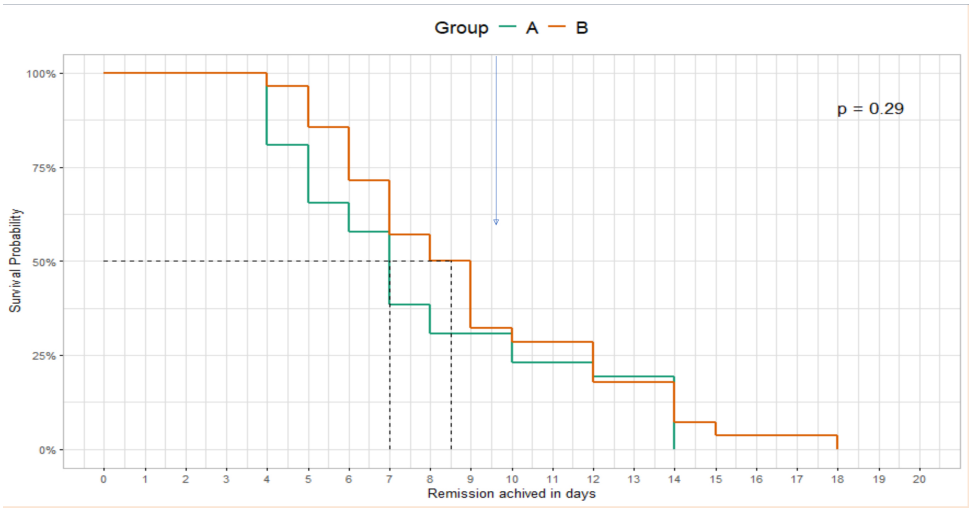


Fig 2. Kaplan-Meier survival analysis curve showing no statistical difference between the two groups and proving the null hypothesis

## Results and Analysis

All continuous variables such as age, age at first attack, number of relapses, duration of taking immunosuppressant therapy, and number of relapses before enrolment were subjected to t-test. For all these variables the p-value was found to be >0.05, hence there was no statistical difference between the two groups.

A chi-square test was performed for the categorical variables such as gender and current diagnosis which showed a p-value of 0.5, therefore there was no statistical association between the two groups.

Hence, both groups were comparable.

- At 6 months of follow-up, a **higher** cumulative proportion of patients with **relapse** were seen in **Group B** which received only prednisolone (21/25; 84%) as compared to Group A which received both prednisolone and steroid-sparing agent (15/24; 62%).
- The crude relative risk calculated was 1.35. This value signifies that the participants in Group B had **35%** more relapses than Group A with a p-value approaching statistical significance(**p-0.08**)
- Major infections during the follow-up period

After 6 months of follow-up, both groups did not have major infections or any adverse

## Conclusions

1. **There was no difference in achieving remission in both groups.**
2. **However, the use of SSA along with PDN in a patient of FRNS/SDNS had fewer relapses compared to the use of PDN alone.**
3. **A multi-centric study with a longer duration of follow-up to validate our findings.**

## References

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