



Initial treatment of idiopathic nephrotic syndrome in children with mycophenolate mofetil vs. prednisone:

A randomized, controlled, multicenter trial (GPN-INTENT Study)  
(geplanter Studienbeginn 01.02.2014)

### Objective

To demonstrate that mycophenolate mofetil as initial treatment is not inferior to standard treatment with prednisone related to relapse rate within 24 months

### Key inclusion criteria:

First episode of SSNS in remission induced by prednisone 60 mg/m<sup>2</sup> BSA per day; age at beginning of study: ≥ 2 years and ≤ 10 years, which corresponds to the typical age range of patients with SSNS.

### Key exclusion criteria:

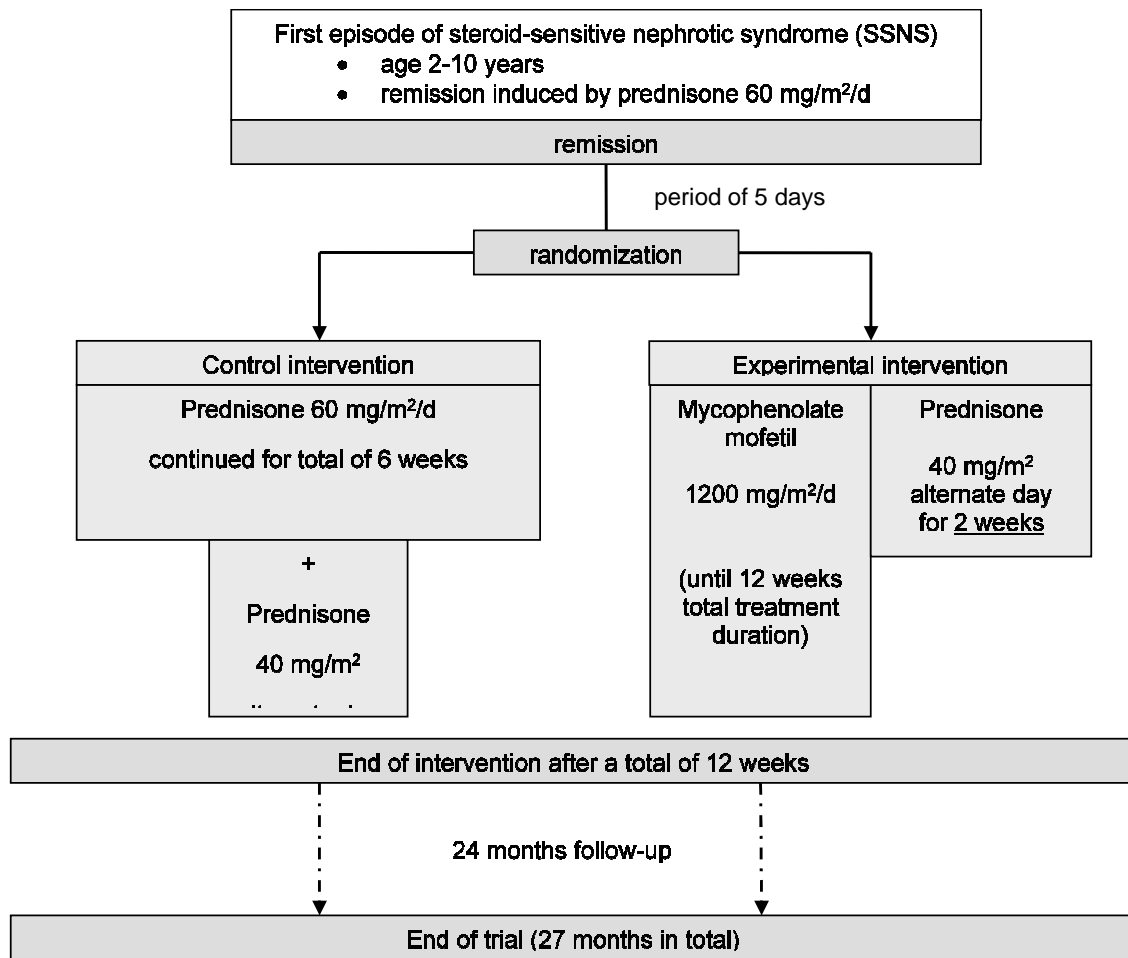
Secondary nephrotic syndrome, estimated glomerular filtration rate (eGFR) <90 ml/min x 1.73 m<sup>2</sup> BSA, ongoing treatment with glucocorticoids or other immunosuppressive drugs at time of first episode of nephrotic syndrome.

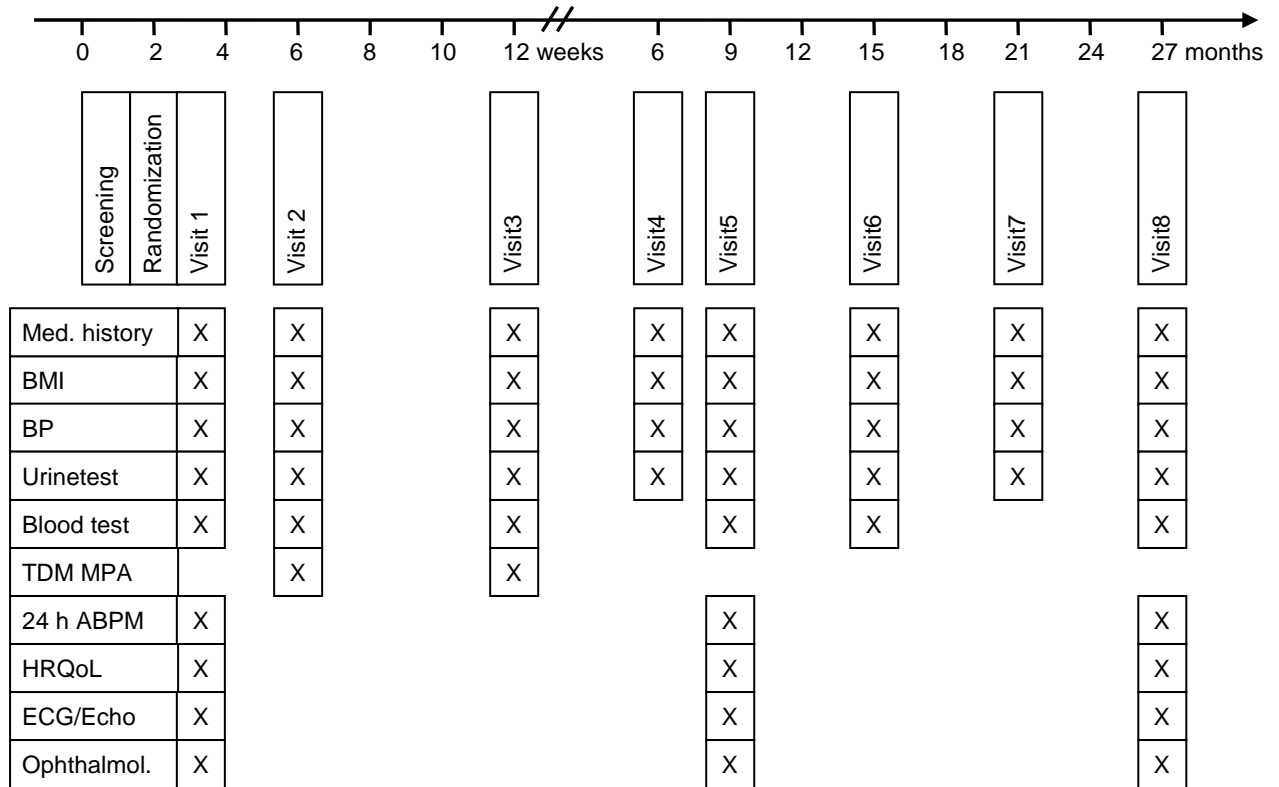
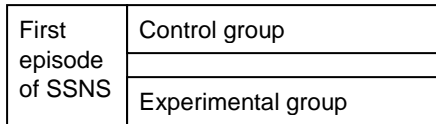
### Primary efficacy endpoint:

Occurrence of relapse within 24 months after end of initial treatment (non-inferiority)

### Key secondary endpoint(s):

- Course of the disease: Time from remission to first relapse; number of relapses; mean relapse rate per patient and year; incidence of frequent relapsers.
- Prednisone-associated toxicity: Cumulative prednisone dose (mg/m<sup>2</sup> BSA); body mass index (standard deviation score); striae; hirsutism; acne; arterial hypertension; disturbances of carbohydrate and lipid metabolism; growth failure; cataract; glaucoma; psychological disturbances
- MMF-associated toxicity: diarrhea; blood cell count disturbances, infections





- Screening: Inclusion criteria fulfilled?
- Randomization: within 5 days of fulfilled inclusion criteria (SSNS)
- Visit 1: at time of randomization (before start with protocol)
- Visit 2: 4 weeks (29-35 d) after start with protocol
- Visit 3: 11 weeks (77-84 d) after begin of treatment with prednisone
- Visit 4: 3 months after start with protocol
- Visit 5: 6 months after start with protocol
- Visit 6: 12 months after start with protocol
- Visit 7: 18 months after start with protocol
- Visit 8: 24 months after start with protocol

## Contact

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