

REduced-dose Steroid PrOtocol for Childhood Nephrotic SyndromE (RESPONSE)

NCT06635720

Status	RECRUITING
Phase	Phase 3
Sponsor	The Hospital for Sick Children
Enrollment	50 participants

Key Eligibility Criteria

Inclusion (8)

- Provide informed consent ± assent
 - Participant age 1-18 years
 - Diagnosis of idiopathic nephrotic syndrome (defined as nephrotic-range proteinuria [first morning or 24-hour urine protein/creatinine ratio ≥ 200 mg/mmol or $\geq 3+$ protein on dipstick] and either hypoalbuminemia [serum albumin ≤ 30 g/L] or edema)
 - Active nephrotic syndrome relapse at time of enrolment (defined as recurrence of nephrotic-range proteinuria [$\geq 3+$ protein on dipstick for ≥ 3 consecutive days OR first morning or 24-hour urine protein/creatinine ratio ≥ 200 mg/mmol AND $\geq 1+$ protein on dipstick for ≥ 3 consecutive days])
 - Ability to take oral medication and willingness to adhere to either study prednisone regimen
- ... and 3 more (see full listing online)

Exclusion (12)

- Prednisone treatment (at any dose) for the active relapse episode for ≥ 2 -days prior to study enrolment
 - Relapse episode within the past 6-weeks (i.e., date of relapse onset within 6-weeks prior to date of enrolment)
 - Current receipt of high-dose maintenance prednisone therapy (dose ≥ 0.6 mg/kg on alternate days or ≥ 0.3 mg/kg daily)
 - Steroid-resistant nephrotic syndrome classification (defined as lack of complete remission within 6-weeks after initiating daily steroid treatment at a standard dose for the initial episode of nephrotic syndrome)
 - Congenital or monogenic cause of nephrotic syndrome (defined as age at diagnosis ≤ 1 -year or known/suspected monogenic cause of nephrotic syndrome)
- ... and 7 more (see full listing online)

Locations (1 total)

The Hospital for Sick Children, Toronto, Ontario, Canada