

PREDNOS 2

PREDNOS 2 is a national multicentre double blind randomised controlled trial of short course daily prednisolone therapy at the time of upper respiratory tract infection in children with relapsing steroid sensitive nephrotic syndrome (SSNS).

Trial details

Full Title: Short course daily prednisolone therapy at the time of upper respiratory tract infection in children with relapsing steroid sensitive nephrotic syndrome

Short Title: PREDNOS 2 study

Aim of the study: To evaluate the effectiveness of a six day course of daily prednisolone therapy at the time of URTI in reducing the development of subsequent nephrotic syndrome relapse in children with relapsing SSNS.

Study design: Double blind randomised controlled trial (RCT).

Sample size: 300 patients will be recruited into the study (150 in each arm) over a 2 year period.

Study Duration: The accrual period is for 2 years and all patients will be followed up for 12 months. The end of trial will be 6 months after the last data capture. The last data capture will be 12 months following recruitment of the last patient. The total study duration is 4 years.

Timeframes: NIHR HTA grant start date: 1st October 2012. Trial set up will take place in 6 months, recruitment will take 24 months, all patients will be followed up for 12 months and 6 months has been allocated for data analysis and report writing. The first patient was randomised on 19th March 2013.

Chief Investigator: Professor Nicholas Webb

Trial Co-Sponsor: Central Manchester University Hospitals NHS Foundation Trust and University of Birmingham (Ref: RG_12-188)

Funding: National Institute for Health Research Health Technology Assessment programme (NIHR HTA) Ref: 11/129/261

EudraCT Number: 2012-003476-39

MHTA CTA: 21761/0281/001-0001 (28th November 2012)

Research Ethics Committee: North West GM Central (Ref: 12/NW/0766) (4th December 2012)

ISRCTN10900733

NIHR CRN Study ID: 13410

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