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Screening the Newborn for Familial Ureteric Reflux

Submission date	Recruitment status	[_] Prospectively registered
23/01/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/01/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
21/12/2009	Neonatal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
93020001

Study information

Scientific Title

Study objectives
Ureteric reflux is an asymptomatic malfunction in the urinary tract: when complicated by urinary infection reflux nephropathy ensues; this causes end-stage renal failure in a significant number

of young adults. To prevent reflux nephropathy, reflux must be detected before infection occurs. The peak incidence for infection is in early infancy, so reflux must be detected in the newborn. Reflux is a familial condition thought to have a sibling prevalence of 40%. A detailed enquiry to elicit the presence of reflux in members of a pregnant mothers family will enable an at risk population to be mustered antenatally. These babies will be subjected to cystography at birth. To determine whether chemoprophylaxis will prevent the onset of renal scarring, babies in whom reflux is detected will be randomised into two groups; one group will be given the therapy, the other will not. Assessment will take place at 3 years and 5 years.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Screening

Health condition(s) or problem(s) studied
Neonatal diseases; Other urological and genital disease

Interventions
Maintenance chemotherapy with trimethoprim 2 mg/kg daily

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Not provided at time of registration

Key secondary outcome(s)
Not provided at time of registration

Completion date
31/05/1995

Eligibility

Key inclusion criteria
Pregnant mothers with a familial ureteric reflux problem

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
06/01/1993

Date of final enrolment
31/05/1995

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
School of Population and Health Sciences
Newcastle upon Tyne
United Kingdom
NE2 4HH

Sponsor information

Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
NHS Executive Northern and Yorkshire (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	09/08/1997		Yes	No