

Screening the Newborn for Familial Ureteric Reflux

Submission date
23/01/2004

Recruitment status
No longer recruiting

☐ Prospectively registered
☐ Protocol

Registration date
23/01/2004

Overall study status
Completed

☐ Statistical analysis plan
[X] Results

Last Edited
21/12/2009

Condition category
Neonatal Diseases

☐ Individual participant data

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

Study design

Randomised controlled trial

Primary study design

Interventional

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