ISRCTN88374184 https://doi.org/10.1186/ISRCTN88374184

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

Contact name
Dr John Scott

Contact details
School of Population and Health Sciences
University of Newcastle upon Tyne
Newcastle upon Tyne
United Kingdom
NE2 4HH

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet

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 measure

Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
06/01/1993

Completion date
31/05/1995

Eligibility

Key inclusion criteria
Pregnant mothers with a familial ureteric reflux problem

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
Not provided at time of registration

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
England

United Kingdom

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)

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
NHS Executive Northern and Yorkshire (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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