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Measuring the outcome of neonatal intensive care: a randomised controlled trial of two methods of data collection.

Submission date 23/01/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/01/2004	**Overall study status** Completed	
Last Edited 08/12/2009	**Condition category** Neonatal Diseases	

Plain English Summary
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Study hypothesis
To compare two simple and inexpensive methods of obtaining long term health status data for high risk newborns. The need for ongoing national outcome data for these babies has been high lighted in a number of national reports. To be successful either method would need to provide outcome data on 95% of children alive at a corrected age of two years.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical approval from the eight local research ethics committees relating to the participating neonatal and community child health services (added 20/11/09)

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet

Condition
Neonatal diseases, Neonatal intesive care outcomes

Interventions
Outcome was measured at 2 years. The two approaches being tested were:
1. A questionnaire about health status completed by parents when the child reached a corrected age of 2 years
2. A questionnaire completed by a clerk based in the local community child service when the child reached a corrected age of 2 years. The clerk used routine information collected about the child.
Both questionnaires were based on a consensus statement developed in the early 1990s about the measurement of health status at 2 years. Nine hospitals in two old NHS regions (Trent and Wessex) were randomly allocated to one of the two methods. Parents gave written consent for

the inclusion of the child prior to discharge. For those in the 'parent arm' intermittent contact was maintained by using birthday and Christmas cards to prompt the family to inform the research team about changes of address. The clerk based in the child health dept. collected data regarding hospital attendances, copies of out patient letters etc. Intermittent telephone contact to the health visitor was also used. At the end of the study a 10% sample of children (half normal, half abnormal) were selected for independent examination to determine if data supplied by both methods were accurate. ONS flagging was used to prevent us contacting a family where the child had died.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Rate of ascertainment of outcome in all areas of development. Target >95%.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/09/1996

Overall study end date
01/04/2000

Eligibility

Participant inclusion criteria
For purposes of the investigation the "at risk" group will be defined as: any baby born less than or equal to 32 weeks gestation.

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
472 (236 in each arm) (added 20/11/09)

Participant exclusion criteria
Does not match inclusion criteria

Recruitment start date
01/09/1996

Recruitment end date
01/04/2000

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Child Health
Leicester
United Kingdom
LE2 7LX

Sponsor information

Organisation
Record Provided by the NHS R&D 'Time-Limited' National Programme Register - Department of Health (UK)

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

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

Funder(s)

Funder type
Government

Funder Name
NHS Mother and Child Health National Research and Development Programme (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	01/12/2001		Yes	No