

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 08/12/2009	Condition category Neonatal Diseases	<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Study objectives

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

Health condition(s) or problem(s) studied

Neonatal diseases, Neonatal intensive 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

Completion date

01/04/2000

Eligibility**Key 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)

Key exclusion criteria

Does not match inclusion criteria

Date of first enrolment

01/09/1996

Date of final enrolment

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