

Study to examine the effects of different styles of consent documentation on parental understanding and recruitment of babies in neonatal research

Submission date 16/04/2007	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 16/07/2007	Overall study status Completed	☐ Statistical analysis plan
		☒ Results
Last Edited 09/10/2014	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

2001/R/NE/11

Study information

Scientific Title

Study objectives

When parents of newborn infants are approached for consent to enter their baby in a research trial, shorter and less complex documents are more effective in terms of:

1. Parental understanding of the important details of the research and implications for their baby, and
2. Recruitment of infants to the research study

Ethics approval required

Old ethics approval format

Ethics approval(s)

Lothian Research Ethics Committee, 01/02/2002, ref: LREC//2001/6/54

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Other

Health condition(s) or problem(s) studied

Neonatal research

Interventions

Two consent forms and information sheets, used in:

- A. United States of America, and
- B. Edinburgh

For the NEOPAIN Multicentre Trial will be tested. The NEOPAIN Trial was an international, randomised, double blind, placebo-controlled trial of routine morphine infusion versus placebo in ventilated preterm infants. The primary outcomes were published in the Lancet in 2004.

Parents will be asked to imagine that their infant was eligible for the study and will be randomised to one of the two forms (A or B), with or without a verbal explanation about the study. After reading the study documentation, they will answer a questionnaire to investigate their understanding, satisfaction and willingness to enrol their infant in the hypothetical study.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Parental understanding of the important points of the research study.

Key secondary outcome(s))

1. Parental satisfaction with information given
2. Parental willingness to allow their baby to participate in research on the basis of the information given

Completion date

31/07/2002

Eligibility

Key inclusion criteria

Parents of infants admitted to the Neonatal Unit within the first 72 hours of life, but not expected to require ventilation.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Parents of infants requiring ventilation
2. Parents who are unable to read or speak English

Date of first enrolment

30/11/2001

Date of final enrolment

31/07/2002

Locations

Countries of recruitment

United Kingdom

Scotland

Study participating centre

Neonatal Unit

Edinburgh

United Kingdom

EH16 4SA

Sponsor information

Organisation

Royal Infirmary of Edinburgh (UK)

ROR

<https://ror.org/009bsy196>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded (Edinburgh)

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?
Abstract results				No	No