ISRCTN56014081 https://doi.org/10.1186/ISRCTN56014081

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

Submission date	Recruitment status	[_] Prospectively registered
16/04/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
16/07/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
09/10/2014	Neonatal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Neil McIntosh

Contact details
Neonatal Unit
Royal Infirmary of Edinburgh
51 Little France Crescent
Old Dalkeith Road
Edinburgh
United Kingdom
EH16 4SA
neil.mcintosh@ed.ac.uk

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

Primary study design
Interventional

Study design
Randomised controlled trial

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