

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

<b>Submission date</b> 16/04/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 16/07/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 09/10/2014	<b>Condition category</b> Neonatal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## **Secondary identifying numbers**

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

## **Secondary study design**

Randomised controlled trial

## **Study setting(s)**

Hospital

## **Study type(s)**

Other

## **Participant information sheet**

## **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 measure**

Parental understanding of the important points of the research study.

**Secondary outcome measures**

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

**Overall study start date**

30/11/2001

**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

**Age group**

Adult

**Sex**

Both

**Target number of participants**

40

**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**

Scotland

United Kingdom

**Study participating centre****Neonatal Unit**

Edinburgh

United Kingdom

EH16 4SA

**Sponsor information****Organisation**

Royal Infirmary of Edinburgh (UK)

**Sponsor details**

Neonatal Unit

51 Little France Crescent

Old Dalkeith Road

Edinburgh

Scotland

United Kingdom

EH16 4SA

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.nhsllothian.scot.nhs.uk/hospitals/rie.asp>

**ROR**

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

**Funder(s)****Funder type**

Other

**Funder Name**

Investigator initiated and funded (Edinburgh)

## 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?
<a href="#">Abstract results</a>				No	No