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Cord Pilot Trial

Submission date 28/02/2013	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/02/2013	**Overall study status** Completed	
Last Edited 25/02/2019	**Condition category** Pregnancy and Childbirth	

Plain English summary of protocol

Background and study aims
In the UK one in every 70 babies is born more than eight weeks before their due date (very preterm). These very premature babies have immature lungs, and often need help with breathing, feeding and keeping warm. Usually at the birth of a premature baby, the umbilical cord is clamped and cut straight away, the baby is placed in a plastic wrap to retain heat, and then cared for by the neonatologist (a doctor or nurse who is a specialist in the care of newborn babies) on a special table at the side of the room. Clamping the cord stops blood flow between the placenta (organ that connects the developing foetus to the uterine wall to allow nutrient uptake, waste elimination, and gas exchange via the mother's blood supply) and the baby. If the cord is not clamped straight away, this blood flow may continue for several minutes, potentially transferring blood from the placenta to the baby. Waiting a few minutes before clamping the cord may help the baby to adjust to life outside the womb. As it is not known when the best time to clamp the cord for very preterm births is, this study is being done. The study is comparing clamping the cord after at least two minutes (deferred cord clamping) with clamping the cord within 20 seconds. For deferred cord clamping, care for the baby will be provided at the woman's bedside. If the cord is clamped within 20 seconds, the neonatal team will choose whether care for the baby is provided at the woman's bedside or at the side of the room. In both cases the baby will receive the same care at birth, just in different places. This is an initial small study to help decide whether it would be possible to do a much larger trial. Finding out which of the two approaches to care is better for babies and their mothers will need the large study. Information from this study will help the researchers to conduct the large study well.

Who can participate?
Women who are expected to give birth more than eight weeks before their due date

What does the study involve?
Women who take part in the study are randomly allocated to one of the two groups: (1) cord clamping after at least two minutes, or (2) cord clamping within 20 seconds. If the cord is clamped after at least two minutes, care for the baby is provided at the bedside. If the cord is clamped within 20 seconds, the neonatal team choose whether care for the baby is provided at the woman's bedside or at the side of the room. Women who take part in the study are asked to complete a short postal questionnaire six weeks after the birth, and another one year after the birth. Around the child's second birthday the parents are contacted to complete another questionnaire and to arrange a visit to find out how their child is doing.

Where is the study run from?
Nottingham Clinical Trials Unit (UK)

When is the study starting and how long is it expected to run for?
March 2013 to September 2017

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
13070; 108150; 12OB006

Study information

Scientific Title
Immediate cord clamping versus deferred cord clamping for preterm birth before 32 weeks gestation: a pilot randomised trial

Acronym
CORD

Study objectives
The primary hypothesis is that for children born before 32 weeks gestation immediate cord clamping is associated with higher death or neurosensory disability at two years of age

(corrected for gestation at birth) than deferred cord clamping. A trial to test this hypothesis would need to be large and multicentre. This protocol is for a pilot trial to assess the feasibility such a study.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee East Midlands - Nottingham 2, 23/07/2012, ref: 12/EM/0283

Study design
Randomised trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Reproductive Health and Childb, Generic Health Relevance and Cross Cutting Themes; Subtopic: Reproductive Health and Childb (all Subtopics), Generic Health Relevance (all Subtopics); Disease: Reproductive Health & Childbirth, Paediatrics

Interventions
1. Deferred cord clamping: clamping the cord after at least two minutes
2. Immediate cord clamping: clamping the cord within 20 seconds

Intervention Type
Procedure/Surgery

Primary outcome(s)
Feasibility outcomes for the original pilot trial:
1. Number of women recruited in each hospital
2. Proportion of potentially eligible women recruited
3. Reasons for non-recruitment (medical, parental, logistic, other)
4. Spectrum of gestational age and neonatal outcome among recruits
5. Compliance with the trial interventions, and reasons for non-compliance
6. Completeness of data collection for main outcomes
7. Views of women and their partners on recruitment, randomisation and the interventions
8. Proportion lost to follow up after discharge from hospital, and reasons for loss to follow up

Added 01/07/2016:
As the primary outcomes planned for the main Cord Trial were death and intraventricular haemorrhage, these were the pre-specified main outcomes for the analysis by allocated group for the Cord Pilot Trial.

Key secondary outcome(s))
No secondary outcome measures

Completion date

01/09/2017

Eligibility

Key inclusion criteria
Women likely to have a live birth before 32 weeks gestation, regardless of mode of birth or whether cephalic or breech presentation

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Monochorionic twins (from an ultrasound scan) or clinical evidence of twin-twin transfusion syndrome
2. Triplets or higher order multiple pregnancy
3. Known congenital malformation

Date of first enrolment
01/03/2013

Date of final enrolment
01/02/2015

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Nottingham Clinical Trials Unit
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation
Nottingham University Hospitals NHS Trust (UK)

ROR
https://ror.org/05y3qh794

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (UK) - Programme Grants for Applied Research; Grant Codes: RP-PG-0609-10107

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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?
Results article	results	26/04/2017		Yes	No
Results article	results	01/01/2018		Yes	No
	1-year follow-up results	21/02	25/02		

Results article		/2019	/2019	Yes	No
Protocol article	protocol	30/06 /2014		Yes	No
Protocol article	protocol update	14/09 /2015		Yes	No
Other publications	women's views and experiences of two alternative consent pathways	09/09 /2017		Yes	No
Participant information sheet	Participant information sheet	11/11 /2025	11/11 /2025	No	Yes
Protocol file	version v6.2	08/09 /2016	10/11 /2016	No	No
Study website	Study website	11/11 /2025	11/11 /2025	No	Yes