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DElayed COrd CLAmping versus early cord clamping in preterm infants born between 24 and 34 weeks

Submission date
06/10/2013

Recruitment status
No longer recruiting

Registration date
10/12/2013

Overall study status
Completed

Last Edited
10/12/2013

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Prematurity is responsible for more than half of all neonatal deaths. Advances in neonatal care have dramatically improved survival of extremely premature infants but there remains a significant risk of handicap and disability in survivors and an associated social and economic burden. Although all births before 37 weeks of gestation are defined as preterm, most damage and death occurs in infants delivered before 34 weeks.
The optimal timing of cord clamping in preterm infants is still the subject of continuing debate, not only due to the potential risks (hyperbilirrubinemia, polycythemia and respiratory grunting) but also in order to hand neonates over the neonatal team for resuscitation.
There is a strong association between hypotension and intraventricular hemorrhage, patency of the ductus arteriosus and necrotizing enterocolitis. It seems that a decrease in blood volume at the time of delivery would negatively influence blood pressure. Furthermore, about 30-40% of very low birth weight (VLBW) infants experience some delay in motor functioning sometime during childhood. Hypovolemia secondary to early cord clamping, might be disruptive to the developing brain resulting in a motor delay.
The aim of this study is to help decide the best time to clamp the umbilical cord in preterm babies below 34 weeks, either early (within 10 seconds) or delayed cord clamping (45-60 minutes), analyzing any differences in blood test the first week of life and any neurosensory disability at the age of two-three years old.

Who can participate?
Women who are expected to give birth below 34 weeks of gestation.

What does the study involve?
Pregnant women will be randomly allocated to one of the two groups: cord clamping within 10 seconds or cord clamping 45-60 seconds after birth.
A blood test is taken 48 hours and 7 days after birth.
Around the age of two-three years old, the parents will be contacted to book an appointment with
the pediatrician for a neurological follow up.

What are the possible benefits and risks of participating?
Risks to participants are minimal because the intervention on the babies it is unlikely to cause any damage. All the babies will be born in a very safety environment with paediatric assistance at birth-time and will be moved to the Neonatal Intensive Care Unit immediately, in case they need it.

Where is the study run from?
Department of Obstetrics and Gynecology-Neonatal Intensive Care Unit, Clinic University Hospital Virgen de la Arrixaca, Murcia (Spain)

When is the study starting and how long is it expected to run for?
The study started in February 2011 and will continue to recruit women until September 2014.

Who is funding the study?
Sistema Murciano de Salud, Spain

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
Randomized study of delayed cord clamping versus early cord clamping in preterm infants born between 24 and 34 weeks

Acronym
DECOCLA

Study objectives

To evaluate the effect of timing of umbilical cord clamping on neonatal venous haematocrit, maternal postpartum haemorrhage and neurosensory disability at two-three years of age.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee CEIC Clinic University Hospital Virgen de la Arrixaca; 21 December 2010

Primary study design
Interventional

Study design
Randomized trial

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Topic: Reproductive Health, Disease: Reproductive Health & Childbirth, Paediatrics

Interventions
Particpants are randomized to two groups:
1. Early cord clamping: clamping of the cord within ten seconds after birth
2. Delayed cord clamping: clamping of the cord 45-60 seconds after birth

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Evaluation of neonatal hemoglobin, hematocrit and bilirrubin levels within the first 7 days after birth

Key secondary outcome(s)
1. Neonatal hemoglobin, hematocrit and ferritin at six months of life will be evaluated by blood sampling
2. Neonatal complications (Intraventricular hemorrhage, necrotizing enterocolitis, retinopathy, sepsis, respiratory problems, days on ventilation or oxygen, need for phototherapy, transfusions) and days in the neonatal intensive care will be evaluated by medical history review
3. Cardiac output in the first week after birth will be measured by echocardiography
4. Blood loss in the mother (blood test 48 hours after birth)
5. Neurodevelopmental assessment of newborns at the age of two-three years in both groups of the study will be test by Bayley Scales of Infant Development

Completion date
01/09/2014

Eligibility

Key inclusion criteria
Women will be eligible for the study if they are likely to have a live birth before 34 weeks gestation, regardless of mode of birth or whether cephalic or breech presentation, singleton or dichorionic pregnancies.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Major fetal abnormalities (defined as those that are lethal or require prenatal or postnatal surgery)
2. Fetal growth restriction
3. Monochorionic twins
4. Maternal pathology (pregestational Diabetes, severe cardiopathy, etc)
5. Infectious disease, hypertension and/or preeclampsia, obstetrics complications (abruptio, etc)

Date of first enrolment
01/02/2011

Date of final enrolment
01/09/2014

Locations

Countries of recruitment
Spain

Study participating centre
C/Alhelies 4. Edif. Al Andalus 3E
El Ranero
Spain
30009

Sponsor information

Organisation
Clinic University Hospital Virgen de la Arrixaca (Spain)

ROR
https://ror.org/058thx797

Funder(s)

Funder type
Government

Funder Name
Murcia Health Service [Servicio Murciano de Salud (SMS)], Murcia (Spain)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration