

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

<b>Submission date</b> 06/10/2013	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 10/12/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 10/12/2013	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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 to 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?

Catalina De Paco Matallana  
Katy.depaco@gmail.com

## Contact information

### Type(s)

Scientific

### Contact name

Dr Catalina De Paco Matallana

### Contact details

C/Alhelies 4. Edif. Al Andalus 3E  
El Ranero  
Spain  
30009  
+34676672617  
katy.depaco@gmail.com

## 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**

Participants 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 bilirubin 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