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Time of the THIrd Stage of labour after early cord CLAMPing versus delayed cord clamping at term

Submission date	Recruitment status	[ ] Prospectively registered
21/04/2014	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
20/06/2014	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
20/06/2014	Pregnancy and Childbirth	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The optimal time to clamp the umbilical cord still remains controversial. Although delayed cord clamping after 30 seconds has significant health benefits, this practice is not widely used. The proposed advantages for early cord clamping are a reduction of postpartum haemorrhage (excessive bleeding following delivery) and also the possibility of analysing the acid-base status in the umbilical cord artery and vein after birth, which is very important for paediatricians and obstetricians. On the other hand, delayed cord clamping is associated with a reduction of anaemia in childbirth. However, there have been no studies regarding any differences between the time of the third stage of labour and the moment we clamp the umbilical cord. The aim of this study is to investigate any differences between the time of the third stage of labour and the umbilical cord clamping.

Who can participate?
Women who are expected to have a normal vaginal birth after 37 weeks of gestation.

What does the study involve?
Pregnant women will be randomly allocated to one of the two groups: either cord clamping within 10 seconds after birth or cord clamping at 2 minutes after birth. Also, the time of the third stage of labour will be measured and, in the meantime, blood will be taken from the umbilical cord artery and the umbilical cord vein. 48 hours after delivery, a maternal blood test will be also performed to find any differences between both groups of the study in terms of postpartum haemorrhage.

What are the possible benefits and risks of participating?
Risks to participants are minimal because the intervention on either the babies or the mothers is unlikely to cause any damage. All the babies will be born in a very safety environment with midwives and paediatricians if they are needed, as all interventions will be performed in normal deliveries.

Where is the study run from?
Clinic University Hospital Virgen de la Arrixaca (Spain).

When is the study starting and how long is it expected to run for?
The study ran from July 2013 to May 2014.

Who is funding the study?
Murcia Health Service (Spain).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Study information

Scientific Title
Time of the third stage of labour after early cord clamping versus delayed cord clamping at term: a randomized study

Acronym
THISCLAMP

Study objectives
To evaluate the effect of timing of umbilical cord clamping on the timing of the third stage of labour in newborns at term.

Ethics approval required
Old ethics approval format

Ethics approval(s)
CEIC Clinic University Hospital Ethics Committee, Virgen de la Arrixaca; 2013

Primary study design
Interventional

Study design
Randomized trial

Study type(s)
Other

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 10 seconds after birth
2. Delayed cord clamping: clamping of the cord 2 minutes after birth

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Evaluation of the time of the third stage of labour in both groups of the study measured using a stopwatch.

Key secondary outcome(s)
Acid-base state in the umbilical artery and vein in both groups of the study. This is measured using Plastipak syringes for the blood collection from the umbilical cord and an automatic blood gas analyzer.

Completion date
31/05/2014

Eligibility

Key inclusion criteria
Women with singleton pregnancies will be eligible for the study if they are likely to have a non-instrumental vaginal delivery after 37 weeks gestation

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. Twin pregnancies
4. Maternal pathology (pregestational diabetes, severe cardiopathy, etc)
5. Infectious disease, hypertension and/or preeclampsia, obstetrics complications (abruptio, etc)

Date of first enrolment
01/07/2013

Date of final enrolment
31/05/2014

Locations

Countries of recruitment
Spain

Study participating centre
Clinic University Hospital Virgen de la Arrixaca (Spain)
El Palmar (Murcia)
Spain
30120

Sponsor information

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

ROR
https://ror.org/055bn0x53

Funder(s)

Funder type
Hospital/treatment centre

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