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Effect of timing of cord clamping on postnatal packed red blood cells value and clinical outcome in term newborns: a randomised controlled trial

Submission date 18/02/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 02/03/2005	**Overall study status** Completed	
Last Edited 18/02/2008	**Condition category** Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Study objectives
To determine the effect of timing of umbilical cord clamping on neonatal venous haematocrit, clinical outcome and maternal postpartum haemorrhage.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The trial was approved by the ethics committees of both hospitals (Hospital Italiano de Buenos Aires protocol number: 681/2002).

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Timing of cord clamping on newborns at term

Interventions
1. Early cord clamping within the first 15 seconds of life
2. Cord clamping at first minute of life
3. Cord clamping at third minute of life

Intervention Type
Other

Phase
Not Specified

Primary outcome measure

Venous haematocrit six hours after birth.

Secondary outcome measures
1. Neonatal haematocrit at 24 - 48 hours of age
2. Plasma bilirubin level at 24 - 48 hours of age
3. Early neonatal morbidity (tachypnea, respiratory grunting, respiratory distress, jaundice, seizures, sepsis, necrotising enterocolitis, neonatal death)
4. Admission to Neonatal Intensive Care Unit
5. Length of newborn hospital stay
6. Any neonatal disease that occurs between birth and one month of age
7. Weight and type of feeding at one month of age
8. Postpartum maternal blood loss volume
9. Maternal haematocrit level at 24 hours postpartum

Overall study start date
27/11/2002

Completion date
28/04/2003

Eligibility

Key inclusion criteria
Women were eligible if they had uneventful cephalic vaginal or cesarean section delivery with the following characteristics:
1. Singleton pregnancy at term
2. No evidence of clinical disease (diabetes, preeclampsia, hypertension) or any other complications
3. No evidence of congenital malformations or intrauterine growth restriction (estimated foetal weight less than 10th percentile)

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
276

Key exclusion criteria
Does not comply with above inclusion criteria

Date of first enrolment
27/11/2002

Date of final enrolment

28/04/2003

Locations

Countries of recruitment
Argentina

Study participating centre
Pueyrredón 985
Rosario
Argentina
2000

Sponsor information

Organisation
United Nations Children's Fund (UNICEF) (Argentina)

Sponsor details
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Sponsor type
Research organisation

Website
http://www.unicef.org/argentina/

ROR
https://ror.org/02dg0pv02

Funder(s)

Funder type
Research organisation

Funder Name
United Nations Children's Fund (UNICEF) (Argentina)

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?
Results article	Results	01/04/2006		Yes	No