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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

Registration date
02/03/2005

Overall study status
Completed

Last Edited
18/02/2008

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

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).

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

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(s)
Venous haematocrit six hours after birth.

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

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)

ROR
https://ror.org/02dg0pv02

Funder(s)

Funder type
Research organisation

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

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	01/04/2006		Yes	No