

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	<input type="checkbox"/> Prospectively registered
Registration date 02/03/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 18/02/2008	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

Protocol serial number

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

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