Cord Clamping Study - Mpongwe (Zambia).

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25019

Source
NTR

Brief title
N/A

Health condition

The study takes place in Mpongwe District, a rural region of the Copperbelt Province in Zambia, approximately 1000m above sea level. Malaria transmission in this area is holoendemic. The rainy season, which is associated with peak malaria transmission, occurs from November to April.

Sponsors and support

Primary sponsor: N/A
Source(s) of monetary or material Support: Liverpool-Amsterdam Cooperation Fund

Intervention

Outcome measures

Primary outcome

Primary endpoints with respect to haematological status are the post-treatment Hb level in relation to pre-treatment values and the proportion of non-anaemic infants at respectively

two, four and six months after birth.

Secondary outcome

Secondary outcome measures include possible side effects of DCC in infants (PCV changes 1 day postpartum; clinical signs of hyperviscosity syndrome and hyperbilirubinaemia) and mothers (Hb level one day after delivery in relation to antenatal values).

Study description

Background summary

This review evaluates the potential of delayed cord clamping for improving iron status and reducing anaemia in term infants, and for increasing the risk of polycythaemia and hyperbilirubinaemia. We applied a strict search protocol for identifying controlled trials of early versus late cord clamping. Four trials from developing and four trials from industrialised countries were finally assessed. Two of the four studies from developing countries found a significant difference in infant haemoglobin levels at 2-3 months of age in favour of delayed cord clamping. This difference was more marked when mothers were anaemic. Three of four studies from industrialised countries showed a significant difference in haematocrit levels in favour of delayed clamping. Although meta-analysis showed an increased risk for hyperbilirubinaemia of 12%, no studies reported the need to apply phototherapy or perform exchange transfusion. We conclude that delayed cord clamping in term infants, especially in anaemic mothers, increases infant haemoglobin concentration by 2-3 months of age and reduces anaemia risk, without an associated increased risk of perinatal complications.

Study objective

Anaemia is recognized as an important cause of morbidity and mortality in underfives. When associated with iron deficiency, anaemia may impair mental and motor development. There are indications that with iron therapy anaemic children fail to catch up to non-anaemic children. Primary prevention of iron deficiency and malaria in young children could have substantive effect on reducing child mortality and morbidity.

Key strategies for the reduction of infant anaemia are: iron supplementation in pregnancy and infancy; iron-fortification of infant formula; chemoprophylaxis and prompt anti-malarial treatment in pregnancy and infancy; and use of insecticide-treated nets to reduce exposure to malaria. Combinations of the aforementioned strategies can synergistically improve anaemia. However, most have had limited success in developing countries due to financial, logistic and technical constraints.
In view of this there is interest in improving the iron status of infants by enhancing their red cell mass with late umbilical cord clamping. This intervention is said to increase Hb concentration by 2-3 months of age, especially in infants born to anaemic mothers. Whether this low cost delivery procedure is effective in reducing anaemia in infants from resource-

poor countries that are malaria-endemic has never been evaluated.

Study design

N/A

Intervention

Pregnant women are randomised to either the intervention of delayed cord clamping (DCC) or immediate cord clamping (ICC). ICC is the routine standard of care in Mpongwe Mission Hospital at the time of the trial, and is usually done within 20 s after delivery. Mother-infant couples assigned to this procedure are thus considered the control group. In the DCC group the umbilical cord is clamped after the cord stops pulsating. The exact time is recorded by use of a stopwatch. A recently performed pilot study showed that cord pulsations normally cease after 3.5 minutes. Following vaginal birth the infant is placed between the legs of the mother (approximately 15 cm below the vaginal introitus), dried, and wrapped in a warm towel.

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Eligibility criteria

Inclusion criteria

Full term pregnant women delivering in Mpongwe Mission Hospital are candidates for inclusion in the study.

Exclusion criteria

1. Twin pregnancy;

2. History of post partum haemorrhage (PPH) > 500 ml;

3. Gestational diabetes;

4. (Pre)eclampsia;

5. Placental separation before delivery;

6. Caesarean section;

7. Tight nuchal cord;

8. Need for neonatal resuscitation;

9. Major congenital abnormalities (e.g. neural tube defects).

Criteria 1-4 are applied before randomisation.

Criteria 5-9 can only be assessed after randomisation.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	01-05-2004
Enrollment:	91
Type:	Actual

Ethics review

Positive opinion Date:	25-09-2005
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL384
NTR-old	NTR424
Other	: N/A
ISRCTN	ISRCTN48735857

Study results

Summary results

1. Trop Med Int Health. 2007 May;12(5):603-16.

2. van Rheenen P, Brabin BJ. Late umbilical cord clamping as an intervention for reducing iron deficiency anaemia in term infants in developing and industrialised countries: a systematic

review. Ann.Trop.Paediatr. 2004;24:3-16.