

Cord Clamping Study - Mpongwe (Zambia)

Submission date 22/11/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 22/11/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 13/08/2009	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

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NTR424

Study information

Scientific Title

Study objectives

Anaemia is recognized as an important cause of morbidity and mortality in under fives. 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 haemoglobin (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.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from local medical ethics committee

Study design

Randomised single blind active controlled parallel group trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Prevention

Participant information sheet

Health condition(s) or problem(s) studied

Pregnancy

Interventions

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.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Post-treatment Hb level in relation to pre-treatment values and the proportion of non-anaemic infants at two, four and six months after birth.

Secondary outcome measures

Possible side effects of DCC in infants (Packed Cell Volume [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).

Overall study start date

01/05/2004

Completion date

31/01/2005

Eligibility**Key inclusion criteria**

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

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

91

Key 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.

Date of first enrolment

01/05/2004

Date of final enrolment

31/01/2005

Locations

Countries of recruitment

Netherlands

Zambia

Study participating centre

Brinklaan 6

Groningen

Netherlands

9722 BC

Sponsor information

Organisation

Liverpool School of Tropical Medicine (UK)

Sponsor details

Pembroke Place

Liverpool

England

United Kingdom

L35QA

Sponsor type

University/education

ROR

<https://ror.org/03svjbs84>

Funder(s)

Funder type

Other

Funder Name

Liverpool-Amsterdam Cooperation Fund

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	01/05/2007		Yes	No