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Cord Clamping Study - Mpongwe (Zambia)

Submission date
22/11/2005

Recruitment status
No longer recruiting

Registration date
22/11/2005

Overall study status
Completed

Last Edited
13/08/2009

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

Protocol serial number
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

Study type(s)
Prevention

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(s)
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.

Key secondary outcome(s))
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).

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

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

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
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9722 BC

Sponsor information

Organisation
Liverpool School of Tropical Medicine (UK)

ROR
https://ror.org/03svjbs84

Funder(s)

Funder type
Other

Funder Name
Liverpool-Amsterdam Cooperation Fund

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	01/05/2007		Yes	No