Cord Clamping Level Above or Below Mother's Perineum

NCT02659605

Version Date: 02/29/2016

Objective: To determine if delayed cord clamping above the perineum has an effect on neonatal hematocrit when compared to delayed cord clamping below the perineum in Pre-term spontaneous vaginal deliveries

Mentor: Dr. Pamela Berens

BACKGROUND:

Delayed cord clamping has been noted to reduce the need for neonatal transfusion, especially in pre-term infants. In addition, the higher hemoglobin levels in newborns serve as a source of newborn iron stores to assist during the first 6 months of life (1). Infants born with lower iron stores may be at risk for iron deficiency during the time of exclusive breastfeeding. Delaying cord clamping has been shown to improve fetal hemoglobin levels around the time of birth (6,7). These studies have typically been performed with the infant kept either at or below the level of the placenta. Potential adverse effects related to delayed cord clamping include: increased post-partum hemorrhage (this effect has not been supported by evidence) and increased risk of therapy for newborn jaundice (which has been noted in some studies looking at delay) (8).

Skin to skin contact at the time of birth, however also has purported benefits relating to maternal – infant attachment. Additionally, this allows for a family centered experience with the infant placed immediately on the maternal abdomen and allows the father or other family member to participate in the cord cutting. The positioning for this with the infant on the maternal abdomen, theoretically places the infant at a higher level than the placenta.

The mechanism of transfusion to infant from the placental is incompletely understood. It is believed to be related to pulsatility from the cord, but the importance of gravity in this process is unexplored. It is therefore unclear if positioning the infant above the placenta on the maternal abdomen would have any influence on the effectiveness of the transfer of blood.

Study Design:

This study will compare the difference in neonatal hematocrit with delayed cord clamping above vs. below the perineum, in infants who are born via term spontaneous vaginal deliveries. Delayed cord clamping below the perineum is an accepted clinical practice in obstetrics and gynecology; however, delayed cord clamping above the perineum has not yet been studied. Delayed cord clamping above the perineum will provide the benefit of immediate skin-to-skin contact between the mother and her newborn. We believe that there will be no clinically significant difference in neonatal hematocrit at 24 hours of life.

We anticipate that we will need thirty two patients in each group for a total of sixty four study participants. Maternal Hgb/Hct prior to delivery will be documented. In addition, maternal demographics (such as age, race, socioeconomic status) and prenatal care information (such as IRB NUMBER: HSC-MS-11-0633

IRB APPROVAL DATE: 08/05/2015

weight change in pregnancy and use of prenatal vitamins and/or other supplementation) will be recorded. Inclusion criteria will include females with pregnancies with 32 0/7-36 6/7 gestation., with single intrauterine pregnancies.

Exclusion criteria will include patients whose infants required immediate resuscitation. Patients will be consented either in clinic or when they present to the labor and delivery ward and the decision has been made to proceed with spontaneous vaginal delivery. Patients will then be randomized into one of two groups: Delayed cord clamping above the perineum (Group A) vs Delayed cord clamping below the perineum (Group B). Due to the nature of the study, blinding of the patients and medical staff present at the time delivery will not be possible, however the delivering physician will not be the same one to collect the blood sample, and maternal knowledge of study group will not change the hematocrit value. In those patients randomized to Group A, after delivery, the infant will be placed on the mother's abdomen and the cord will be clamped 30-45 seconds after delivery of the infant. In those randomized to the B group, the infant will be held below the perineum, and the cord clamped and cut 60-75 seconds after delivery of the infant. To ensure accurate timing of cord-clamping, a designated time-keeper will be designated whose sole responsibility will be to document time of delivery and cord clamping. This time-keeper will announce when 15 seconds are left to cord-clamping and will also begin a count-down at 5 seconds.

Neonatal blood will be obtained at the time of routine newborn screening, approximately 24-hours after delivery, to check the hematocrit. This should not pose any significant risk to the infant, as the blood collection will not require any additional sticks and the additional volume required to check the hematocrit is 250 microliters.

The difference in hematocrit of the two groups will be compared. If there is no significant difference in the neonatal hematocrit, this study can be extended to those infants born via preterm spontaneous vaginal delivery to encourage skin-to-skin contact between mom and baby while waiting to clamp the cord. This contact could be beneficial to both mom and baby, as premature infants are often handed off to the awaiting NICU team for resuscitation or other necessary assessments and/or interventions; and the opportunity for that initial contact is missed.

References:

1) Rabe H, Jewison A, Fernandez Alvarez R, et al. Milking compared with delayed cord clamping to increase placental transfusion in preterm neonates Obstet Gynecol. 2011; 117 (2 part1) 205-211

2) Acra G, Botet F, Palacio M, Carbonell-Estrany X. Timing of umbilical cord clamping: new thoughts on an old discussion. J Matern Fetal Neonatal Med. 2010; 23(11):1274-85 IRB NUMBER: HSC-MS-11-0633

IRB APPROVAL DATE: 08/05/2015

3) Levy T, Blickstein I. Timing of cord clamping revisited. J Perinat Med. 2006; 34(4):293-7

4) Rabe H, Reynolds G, Diaz-Rosello J. Early verses delayed umbilical cord clamping in preterm infants. Cochrane Database Syst Rev. 2004; (4):CD003248

5) Ibrahim HM, Krouskop RW, Lewis DF, Dhanireddy R. Placental transfusion: umbilical cord clamping and preterm infants. J Perinatol. 2000;20(6):351-4

6) Chaparro CM Timing of umbilical cord clamping: effect on iron endowment of the newborn and later iron status. Nutrition Reviews 2011;69 (suppl. 1):530-537

7) Dewey K, Chaparro C. Mineral metabolism and body composition iron status of breast-fed infants. Proceedings of the Nutrition Society 2007;66:412-422

8) McDonald SJ, middleton P Effect of timing of umbilical cord clamping of term infants on maternal and neonatal outcomes. Cochrane Database of Systmatic Reviews 2008 No: CD004074 IRB NUMBER: HSC-MS-11-0633

IRB APPROVAL DATE: 08/05/2015