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Official Study Title: Safety of Immediate Skin-To-Skin Contact after Vaginal Birth in Vigorous Late-Preterm Neonates – A Pilot Study

NCT Number: 03585192

Protocol Date: October 24, 2017

Date of Document: August 21, 2018

Protocol

I. Inclusion Criteria

1. Singletons born 35 0/7 to 36 6/7 weeks GA via vaginal delivery
2. Vigorous - crying, good respiratory effort, good tone
3. No major congenital malformation

II. Recruitment

1. Recruitment will occur at UH MacDonald Women's Hospital.
2. Mothers who meet the inclusion criteria will be tracked in the EMR at time of admission to the Labor & Delivery Unit.
3. Informed consent will be obtained by members of the research team.
    a. Consenting process will occur at the time of Mother's admission to the Labor & Delivery Unit.
    b. Consent will be obtained in Mother's room.
    c. Mother will not be consented if sedated, under distress from laboring process, or clinically unstable per Labor & Delivery Team.

III. Randomization

1. Index cards with **skin** or **warmer** written on them will be placed in opaque, sealed envelopes.
2. The envelopes will be shuffled randomly and numbered 1-120. The envelopes will be kept in chronological order. Extra envelopes containing index cards will be made if needed using the same randomized process. The investigators anticipate needing approximately 30% more randomized envelopes than what has been calculated by our Statistician due to unplanned deliveries in which the Mother was planning to have a vaginal birth and needs to undergo a cesarean section, either the Mother or neonate are unstable after delivery, or Mother's decision to withdrawal from the study. In the event of the above scenarios, an additional Mother-neonate dyad will need to be randomized in order to achieve our goal of 92 neonates for study completion.
3. Envelopes will be stored in the Neonatal Treatment Room adjacent to Operation Room 1 on the Labor & Delivery Unit.
4. After obtaining informed consent and if the Mother is agreeable to participate in this study, a sealed envelope will be brought to laboring room and opened prior to delivery. No one in the delivery room will know what is written on the index card. The envelope will be opened right before delivery.
5. Skin is the intervention group (Group 1) and warmer is the control group (Group 2)
6. **Skin (Group 1)**

    a. If the newborn is vigorous (crying, good respiratory effort, good tone) after vaginal delivery, newborn will be able to go directly to Mother's chest for immediate SSC

    b. A pulse oximeter will be placed on the newborn's right wrist. Saturations will be monitored on a pulse oximeter located next to the Mother's bed.

7. **Warmer (Group 2)**
   a. Newborn will go to the radiant warmer, pulse oximeter placed on newborn's right wrist, and saturations will be monitored on the Panda Warmer.
   b. If stable per Baby RN after 20 minutes of observation, the newborn will be placed on Mother's chest for SSC.
8. In the event that the Mother agrees to the study and is randomized into the control group but requests SSC, Mother will be informed that UH standard of care does not allow this practice for late-preterm neonates outside of this study and the Mother is free to stop participation in the study at any time.
9. Information about how the newborn transitioned after birth will be collected, regardless if neonate is in the skin or warmer group. The information gathered will be analyzed to determine if there are any differences in postnatal transitioning between the two groups of newborns.

IV. Study Methods

Preparation prior to vaginal delivery (all late-preterm neonates)

1. Prepare Mother to receive newborn (bra removed & uncover breasts)
2. Place warm blanket on Mother's abdomen to receive neonate.
3. Pulse oximeter will be turned on and placed bedside to allow uninterrupted contact and positioning between Mother and neonate. Screen is to be visible to Labor & Delivery RN at all times.

Initiate immediate SSC after vaginal birth of vigorous late-preterm neonate – Group 1 (skin)

1. Newborn Nurse will assist Mother with initiating skin-to-skin contact
2. Place nude neonate supine on warm blanket on Mother's abdomen
3. Suction mouth and nose if necessary, dry, & remove wet blanket
4. Place pulse oximeter on right upper extremity, hat, diaper, and cover with warm receiving blanket
5. Assign 1 minute APGAR
6. Any change in clinical status of either Mother (based on clinical judgment by OB Physician or Midwife) or neonate (based on clinical judgment by Pediatric Team or Neonate's RN) will preclude continued SSC and warrant immediate intervention until stabilized.
   a. Interventions to stabilize neonate: repositioning on Mother's chest, ensure unobstructed airway, oral suctioning with bulb syringe if needed, reapply pulse oximeter, & remove from Mother's chest if needed.

Monitoring during postnatal transitioning

Following standard of care, there is a dedicated baby RN that will be continuously assessing the baby in a location consistent with current UH Clinical Practice Guidelines. Routinely, any baby doing SSC is not placed on continuous pulse oximetry. However, for the purposes of this study, we will place all babies (control and experimental groups) on continuous pulse oximetry to ensure safety with SSC. The pulse oximeter will record continuous oxygen saturation and heart rate.

1. Following current standard of care, after drying and stimulating with warm blanket, remove the wet blanket, and place neonate in prone position on Mother's bare chest between breasts in upright position within 5 minutes of birth
2. Monitor neonate's head position and ensure nose is unobstructed
3. Cover with 2-4 layers of warm receiving blankets
4. Assign 5 minute APGAR
5. Neonate to stay on Mother's chest for uninterrupted SSC for at minimum first 60 minutes of life irrespective of timing of first feed. The goal is continuous, monitored SSC within the first 60 minutes of life.
6. Routine vital signs, including pulse oximetry, will be monitored and documented in the EMR until Mother/neonate stable for transfer to antepartum unit. Vital signs will be obtained per current UH protocol (see attachment – Clinical Practice Guideline Care of the Well Neonate). Normal values and assessment data include:
   a. Axillary temperature 36.5-37.5 degrees Celsius
   b. Heart rate of 100 to 180 beats per minute (if not eating or crying)
   c. Regular cardiac rhythm
   d. Respiratory rate of 40-60 breaths per minute
   e. Pulse oximetry parameters per NRP guidelines (see attachment – Foundations of Neonatal Resuscitation).
   f. Any pulse oximetry reading < 85% after 10 minutes of life will require the baby to be repositioned on Mother's chest, ensure unobstructed airway, oral suctioning with bulb syringe if needed, reapply pulse oximeter, & remove from Mother's chest if needed.
   g. Any pulse oximetry reading < 88% at 1 hour of life will require the baby to be repositioned on Mother's chest, ensure unobstructed airway, oral suctioning with bulb syringe if needed, reapply pulse oximeter, & remove from Mother's chest if needed.
   h. Screening and management of postnatal glucose homeostasis will be instituted, as is the current policy at UH MacHouse Women's Hospital, for all late-preterm neonates until 24 hours of life (see attachment – University Hospitals MacDonald Women's Hospital Screening and Management of Postnatal Glucose Homeostasis).
7. Signs of tolerance of postnatal SSC:
   1. Pink or with mild acrocyanosis
   2. Respiratory effort easy, no audible grunting, or visible intercostal retractions
   3. Alert, demonstrating feeding cues, or sleeping comfortably
   4. Well-flexed posture with good tone
8. Any change in clinical status of either Mother (based on clinical judgment by OB Physician or Midwife) or neonate (based on clinical judgment by Pediatric Team or Neonate's RN) will preclude continued SSC and warrant immediate intervention until stabilized.
   1. Interventions to stabilize neonate: repositioning on Mother's chest, ensure unobstructed airway, oral suctioning with bulb syringe if needed, reapply pulse oximeter, & remove from Mother's chest if needed.

Monitoring of late-preterm neonate if randomized to Group 2 (warmer)

1. Initial period of observation (20 minutes) under the radiant warmer per current UH protocol
2. Place pulse oximeter on right upper extremity
3. SSC protocol to be followed as detailed in **(numbers 2-8)**
4. Any change in clinical status of either Mother (based on clinical judgment by OB Physician or Midwife) or neonate (based on clinical judgment by Pediatric Team or Neonate's RN) will preclude continued SSC and warrant immediate intervention until stabilized.
   a. Interventions to stabilize neonate: repositioning on Mother's chest, ensure unobstructed airway, oral suctioning with bulb syringe if needed, reapply pulse oximeter, & remove from Mother's chest if needed.