Cover Page for Protocol

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University of Kansas Medical Center
RESEARCH PROTOCOL INVOLVING HUMAN SUBJECTS
TEMPLATE WITH GUIDANCE

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Study Title: Kangaroo care in the operating room

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I. Purpose, Background and Rationale

A. Aim and Hypotheses

1. Immediate and continuous skin-to-skin contact between mother and baby has been proven to improve the health of both parties. It is standard practice at KU to place the baby immediately on the maternal chest after a vaginal delivery. However, after cesarean birth the baby is first taken to the warmer for assessment and then may or may not be brought to maternal chest after several minutes. There have been good studies looking at kangaroo care (aka immediate skin to skin) during vaginal deliveries, but studies looking at this practice in the OR are lacking. There have been a few small studies that prove it's feasible.

2. Aim: Assess the maternal and infant benefits of kangaroo care in the OR. Randomize women to receive standard OR fetal resuscitation versus immediate skin to skin after scheduled cesarean deliveries of term, singletons. Hypothesis: 1- Immediate skin-to-skin (StS) during cesarean section will decrease the number of pain and anxiolytic medications required during surgery, decrease the maternal rating of pain during cesarean section, and increase the maternal satisfaction score of cesarean section. 2- There will be no difference in the 5-minute Apgar score, neonatal admission to the ICU, maternal infection rate, or QBL between the two groups.

B. Background and Significance

1. Study Significance: We anticipate that our study will demonstrate that Kangaroo care in the OR is safe, feasible and has similar benefits to mom and baby as seen with vaginal deliveries. We hope the study protocol will make everyone feel more comfortable with the practice of immediate StS in the OR. The goal would be to change the nursery protocol for baby resuscitation after cesarean deliveries allowing for standard immediate StS with benefits to mom and baby.
1. Several obstetricians currently working at KU have shared positive experiences with immediate StS after cesarean deliveries performed at other institutions. More and more patients are requesting “gentle cesarean” deliveries because they are educated about the benefits of immediate StS. When proposing we implement this process at KU, we realized there was a paucity of research around kangaroo care in the operating room. The study comes from our team’s desire to improve obstetric care and encourage other institutions to do the same.

2. Literature Review: In 2016, Cochrane published a systematic review looking at if skin-to-skin contact improved breastfeeding rates and helped babies adjust to the outside world. They looked at the results of 46 studies which included almost 4000 mothers and their babies. Overall, their review supports the use of skin-to-skin to encourage breastfeeding. The evidence suggests that early skin-to-skin should be normal practice for healthy newborns including those born by caesarean and babies born early at 35 weeks or more.

   Immediate and continuous skin-to-skin contact between mother and baby encourages the infant to adjust to life outside the womb. Research shows skin-to-skin results in:
   - Higher axillary temperatures and lower risk for hypothermia
   - Higher blood glucose levels and lower risk for hypoglycemia
   - More stable respiratory rates
   - Faster return to physiologically normal heart rate
   - Decreased crying
   - Decreased anxiety for birthing parent
   - Increased self-confidence in mother's parenting ability
   - Stimulation of maternal oxytocin to enhance uterine contractions, access to colostrum and mother-baby bonding – allows mother and baby to smell and feel each other
   - Encouragement of breastfeeding - the warmth, smell and closeness to the breast are associated with easier and longer breastfeeding

   A review article by J. Stevens et al. summarized findings of 7 studies showing that with appropriate collaboration skin-to-skin contact during cesarean surgery can be implemented. These studies also showed trends toward the above benefits which are well documented after vaginal deliveries.

C. Rationale

1. The research clearly supports the practice of immediate skin to skin after vaginal birth; therefore, we anticipate this intervention to have similar benefits after cesarean birth. KUMC is a designated Baby-Friendly hospital. The Baby-Friendly designation process requires verification of policies, curriculum, action plans, quality improvement projects, staff training, and competency verification, as well as a readiness interview and an on-site survey. When implementing immediate StS after vaginal deliveries, the healthcare providers went through training which included techniques to educate and prepare parents. Immediate StS is now standard for all vaginal deliveries at KUMC.

2. Kangaroo care in the OR is understudied and therefore this project will hopefully advance our understanding and comfort with this procedure.
3. We anticipate that implementing immediate StS after cesarean deliveries will benefit both moms and babies.

II. Research Plan and Design

A. Study Objectives: Aim: Assess the maternal and infant benefits of kangaroo care in the OR. Randomize women to receive standard OR fetal resuscitation versus immediate skin to skin after scheduled cesarean deliveries of term, singletons. Hypothesis: Immediate skin-to-skin (StS) during cesarean section will decrease the number of pain and anxiolytic medications required during surgery, decrease the maternal rating of pain during cesarean section, and increase the maternal satisfaction score of cesarean section. We hypothesize there will be no difference in the 5-minute Apgar score, neonatal admission to the ICU, maternal infection rate, or QBL between the two groups.

B. Study Type and Design: Randomized controlled trial (RCT).

C. Randomization will be done by simple randomization. Subjects will be assigned into two groups A and B. Subjects will be assigned to each group purely randomly for every assignment. Randomization will be performed by using an excel file, available here in a read only state: http://cafe.naver.com/easy2know/6427. Allocation concealment will be done with sealed envelopes.

1. Blinding of the physicians, nurses, and study participants is not possible in this study. We do plan to blind the statistician to the treatment. (S)he will not know the treatment name because the treatment name will be hidden, as in A and B.
2. Approximately 300 scheduled, term singleton cesareans are performed annually at KU. Our primary outcome is to detect at 20% difference in satisfaction with the procedure. Power calculation as below:
   - Total n=112 (56 per group)
   - Assumptions
     - Alpha=0.05 (95% confidence interval)
     - Beta=0.20 (80% power)
     - Control group mean (SD) satisfaction 4.0 (1.5)
     - Experimental group mean (SD) satisfaction 4.8 (1.5)

D. **Subject Criteria (See Vulnerable Populations appendix, if applicable):** All patients presenting for delivery at KUMC will be considered as study subjects regardless of race, age, or primary language.
1. Inclusion criteria: All term, singleton scheduled cesarean sections occurring at KUMC.
2. Exclusion criteria: Priority, urgent and emergent cesareans. Planned general anesthesia, fetal anomalies, fetal aneuploidy/genetic syndrome, abnormal fetal dopplers, placental previa, placenta accreta, multiple gestations, preeclampsia with severe features.
3. Withdrawal/Termination criteria: Standard fetal resuscitation protocols will be utilized. There are times where the infant will be brought to the warmer for infant or maternal indications. Examples of infant indications are abnormal vital signs. Maternal indications would include uncontrolled pain or surgical complication.
4. Our patients can be enrolled in studies that involve collection of cord blood after delivery. No studies are currently going on that impact the mode of delivery or infant resuscitation.

E. Specific methods and techniques used throughout the study

1. Laboratory tests: Likert scale for maternal satisfaction and pain scores. Anesthesia record will be analyzed for medications given to mom both before, during and after the cesarean delivery as part of the procedural care. Fetal apgars, skin to skin timing and NICU admission will be obtained from the pediatric nursing records.
2. Study Procedures: Standard, preexisting neonatal resuscitation protocols already in use at KUMC.
3. Routine neonatal care will be utilized in both the control (baby to warmer, delayed StS) and treatment (baby to maternal chest, immediate StS) groups.

F. **Risk/benefit assessment:**
1. Physical risk - none anticipated
2. Psychological risk **–** Our current standard of bringing the baby to the warmer after cesarean birth is hypothesized to result in more maternal anxiety compared to the treatment group receiving immediate StS.
3. Social risk - none anticipated
4. Economic risk - none anticipated
5. Potential benefit of participating in the study
    a. The chance to be randomized to receive immediate StS with newborn and gain the known benefits associated with kangaroo care.
    b. A change in standard practice to improve maternal and newborn care.
    c. Published literature or poster presentation may encourage other institutions to consider immediate StS after cesarean delivery.

G. Location where study will be performed: KUMC labor and delivery.

H. Collaboration (with another institution, if applicable): n/a

I. **Single IRB Review for a Multi-site study (if applicable):** n/a

J. **Community-Based Participatory Research (if applicable**) – n/a

K. **Personnel who will conduct the study, including:**
1. Indicate, by title, who will be present during study procedure(s): Routine care will be performed by the physician, nurses, and techs at KUMC.
2. Primary responsibility for the following activities, for example:
    a. Determining eligibility: PI
    b. Obtaining informed consent: Clinical Research Coordinator
    c. Providing on-going information to the study sponsor and the IRB: PI
    d. Maintaining participant's research records: Clinical Research Coordinator
    e. Completing physical examination: the physicians performing cesarean delivery as part of standard care.
    f. Taking vital signs, height, weight: the nurses and physicians providing routine care to mom and newborn.
    g. Drawing / collecting laboratory specimens: the nurses and physicians providing routine care to mom and newborn.

h. Performing / conducting tests, procedures, interventions, questionnaires: the nurses and physicians providing routine care to mom and newborn.

i. Completing study data forms: the nurses and physicians providing routine care to mom and newborn.

Managing study database: PI and Clinical Research Coordinator.

L. Assessment of Subject Safety and Development of a Data and Safety Monitoring Plan

1. n/a – no more than minimal risk. As per routine care, if StS is determined to be unsafe based on maternal or baby status, it will be terminated at the request of the obstetrician or newborn nurse based on the same standards we use for routine StS practice.
2. If adverse events happen with routine care, they will be reported to the PI and communicated to the IRB. As with any adverse healthcare events, a safety incident (SI) report will be generated by KUMC staff.

III. Subject Participation

A. **Recruitment**:

1. Any patients who deliver at KUMC and meet inclusion criteria will be recruited. These patients may or may not have received prenatal care at KUMC. The obstetricians on staff at KUMC also provide the prenatal care for women at Vibrant Health and Johnson County Health Department. These patients will be included in our research study. We also perform cesarean deliveries for maternal fetal medicine and family medicine patients.
2. The study coordinator will review the L&D OR schedule to identify cases that meet study criteria. Our study coordinator will then call the patients to review the study with them. When feasible, the study coordinator can also come to clinic to recruit patients during their routine prenatal care visits. Lastly, if a patient presents to L&D for a scheduled cesarean but has not been recruited during their prenatal care, they will be introduced to the study while on labor and delivery.
3. Advertisements - n/a
4. Recruitment letter - n/a

B. **Screening Interview/questionnaire**: Chart review will be used at the primary means of screening for inclusion/exclusion criteria.

C. Informed consent process and timing of obtaining of consent

1. During prenatal care, it will be the research coordinator. Informed consent will be performed over the phone or in person. Over the phone consent will utilize Redcap or in person a printed document will be signed by the patient. If a patient presents to L&D for her scheduled, term singleton cesarean delivery without having been informed of the study, she will be informed by the Clinical research coordinator.
2. Personnel involved in the consenting process include the study approved clinical research coordinators. All people involved in consenting patients will be trained in the principals of medical informed consent.
3. No one is consented under duress. Only scheduled, planned cesareans are included in the study.

D. Alternatives to Participation: Routine care will be conducted.

E. **Costs to Subjects:** n/a

F. **How new information will be conveyed to the study subject and how it will be documented:** MyChart(electronic health record) message to study participants.

G. **Payment, including a prorated plan for payment:** n/a

H. **Payment for a research-related injury:** n/a

IV. Data Collection and Protection

A. Data Management and Security:

1. Redcap and Heron. Only the PI and other research personnel identified on the IRB application.
2. All collected information will be de-identified. A code with subject numbers and their corresponding MRNs will be kept in an excel spreadsheet on the P drive.
3. Participants will be assigned a subject number, not identified by name/dob/mrn.
4. The research coordinator will keep the excel spreadsheet code on the p drive.
5. The patient's assigned research participant number (as assigned by the research coordinator after recruitment) will be included in the research tab in the electronic health record. This participant number will be used when the subject's data is entered into redcap survey.
6. Data stored in redcap survey.
7. Mobile devices - n/a
8. No data sent outside KUMC

B. Sample / Specimen Collection: n/a

C. Tissue Banking Considerations: n/a

D. Procedures to protect subject confidentiality: n/a

E. Quality Assurance / Monitoring

1. Data taken from the electronic health record will be used.
2. No third-party monitoring.

V. Data Analysis and Reporting

A. Statistical and Data Analysis: Participant demographics will be summarized using descriptive statistics (proportions and means). Differences between study groups will be assessed using chi-square and t-tests for categorical and continuous variables, respectively. Differences in satisfaction and pain scores between study groups will be assessed using t-tests if the data is normally distributed. If not normally distributed, data will be adjusted by taking the log of the mean scores, or a non-parametric comparison of medians will be conducted. If any clinically important differences exist between the experimental and control groups at baseline, a linear regression model will be constructed allowing us to control differences between groups.

B. **Outcome**: Primary outcome is maternal satisfaction. Improvement in maternal satisfaction with the cesarean delivery will be the criteria for success. We set clinically meaningful difference of 20% improved satisfaction.

C. **Study results to participants**: none

D. **Publication Plan**: Our goal is to publish our RCT in either AJOG or ACOG journals.

VI. Bibliography / References / Literature Cited (choose the applicable title and list citations according to APA or other accepted style in your discipline)

APPENDIX I: VULNERABLE POPULATIONS

I. **Children:** Our consent form will clarify what information we are collecting about the baby. The baby will not be consented, it will be considered parental permission with waived consent of the newborn child.

II. **Pregnant women:** Our project does not impact the standard of care. Inclusion in the study will not impact their pregnancy or surgery.