PROTOCOL SECTION
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Identification Module

Nct Id: NCT06543160
Org Study Id Info:
Id: Grant No.(2023LinShenZi No.123
Organization:
Full Name: Qingdao Municipal Hospital
Class: OTHER
Brief Title: Immediate Skin-To-Skin Contact and Early Breastfeeding During Caesarean Section
Official Title: Immediate Skin-to-Skin Contact and Breastfeeding During Caesarean Section: A Randomized Controlled Trial on Early Neonatal Hypoglycemia in Late Preterm and Term Infants
Status Module

Status Verified Date: 2024-08
Overall Status: COMPLETED
Expanded Access Info:
Has Expanded Access: false
Start Date Struct:
Date: 2023-07-01
Type: ACTUAL
Primary Completion Date Struct:
Date: 2024-05-15
Type: ACTUAL
Completion Date Struct:
Date: 2024-07-20
Type: ACTUAL
Study First Submit Date: 2024-07-31
Study First Submit Qc Date: 2024-08-03
Study First Post Date Struct:
Date: 2024-08-07
Type: ACTUAL
Last Update Submit Date: 2024-08-03
Last Update Post Date Struct:
Date: 2024-08-07
Type: ACTUAL
Sponsor Collaborators Module

Responsible Party:
Type: PRINCIPAL_INVESTIGATOR
Investigator Full Name: Jia Qiao
Investigator Title: RN
Investigator Affiliation: Qingdao Municipal Hospital
Lead Sponsor:
Name: Qingdao Municipal Hospital
Class: OTHER
Oversight Module

Oversight Has Dmc: false
Is Fda Regulated Drug: false
Is Fda Regulated Device: false
Description Module

Brief Summary: Background: Neonatal hypoglycemia is a prevalent and serious condition among late preterm and term infants, which can lead to severe neurodevelopmental consequences if not managed properly. Immediate skin-to-skin contact (SSC) and early initiation of breastfeeding are recognized as effective interventions to stabilize glucose levels and support neonatal adaptation to extrauterine life. However, implementing these practices during cesarean sections (CS) presents challenges due to the need to maintain a sterile surgical environment and logistical complexities.

Objective: This study aims to evaluate the effects of immediate SSC and early breastfeeding initiation during CS on neonatal hypoglycemia and breastfeeding outcomes.

Methods: A randomized controlled trial was conducted with 336 mother-neonate pairs undergoing elective CS. Participants were randomly assigned to either the experimental group, which received immediate SSC and early breastfeeding during CS, or the control group, which received standard care. Blood glucose levels of neonates were monitored at 1, 3, and 6 hours post-birth. Additional outcomes included the time to breastfeeding initiation, duration of the first breastfeeding session, onset of lactogenesis II, and the rate of exclusive breastfeeding during hospitalization.
Detailed Description: Neonatal hypoglycemia is a common condition among late preterm and term infants. It can lead to severe neurodevelopmental consequences if not managed properly. Immediate skin-to-skin contact (SSC) and early initiation of breastfeeding are effective interventions for stabilizing glucose levels and supporting neonatal adaptation to extrauterine life. While these practices are well-documented for their benefits in vaginal births, their implementation during cesarean sections (CS) presents challenges due to the need for maintaining a sterile surgical environment and the logistical complexities involved. The primary objective of this study was to evaluate the effects of immediate SSC and early breastfeeding initiation during CS on neonatal hypoglycemia and breastfeeding outcomes in late preterm and term infants.

This study was designed as a pragmatic, parallel-design, two-arm randomized controlled trial. It was conducted at Qingdao Municipal Hospital in China from July 2023 to July 2024. A total of 336 eligible mother-neonate pairs undergoing elective CS were included in the study.

Participants included mothers aged 18 years or older with a singleton pregnancy and gestational age between 34+1 and 41+6 weeks, undergoing elective CS with epidural or spinal anesthesia, willing to engage in SSC and breastfeeding during and after surgery, and newborns with Apgar scores above 8 at 1 and 5 minutes, a strong sucking reflex, and no critical conditions requiring transfer. Exclusion criteria involved serious pregnancy complications (e.g., placenta previa, eclampsia), conditions hindering SSC initiation (e.g., neonatal asphyxia, maternal excessive bleeding), and previous breast surgeries or medications affecting breastfeeding.

Participants were randomly assigned to either the experimental group (immediate SSC and early breastfeeding during CS) or the control group (standard care) using a block randomization sequence generated by Microsoft Excel 2010. The randomization process was centrally managed, with blinding maintained for staff performing SSC and data collectors, though patient blinding was not feasible.

Interventions:

Experimental Group:

1. SSC and Breastfeeding During CS: Immediately after delivery, the surgical drape was lowered for parents to witness the birth. The neonate was placed prone on the mother's chest and dried within 20-30 seconds. Breastfeeding was initiated as soon as possible, and SSC continued throughout the surgery and for at least 90

minutes post-transfer to the ward.
2. Routine Newborn Care: Included standard newborn care such as eye care, vitamin K1 administration, immunizations, and weighing, conducted before transferring the neonate to the ward.

Control Group:

1. Delayed SSC and Breastfeeding: SSC was initiated within one hour after birth and maintained for at least 90 minutes post-surgery. The neonate was dried within 20-30 seconds after birth and sent to the ward while the mother completed the surgery.
2. Routine Newborn Care: Similar to the experimental group.

Outcome Measures:

Primary Outcome: Incidence of neonatal hypoglycemia, with blood glucose levels monitored at 1, 3, and 6 hours post-birth using the Stat Strip Xpress glucose meter. Hypoglycemia was categorized as mild (\<45 mg/dL), moderate-to-severe (\<36 mg/dL), and severe (\<18 mg/dL).

Secondary Outcomes: Included time to breastfeeding initiation, duration of the first breastfeeding session, onset of lactogenesis II (significant milk secretion perceived by the mother), and rate of exclusive breastfeeding during hospitalization.

Conditions Module

Conditions:
- Neonatal Hypoglycemia

Keywords:
- neonatal hypoglycemia
- skin-to-skin contact
- breastfeeding
- cesarean section
- lactogenesis

Design Module

Study Type: INTERVENTIONAL
Phases:
- NA

Design Info:
Allocation: RANDOMIZED
Intervention Model: PARALLEL
Primary Purpose: SUPPORTIVE_CARE
Masking Info:
Masking: TRIPLE
Who Masked:
- CARE_PROVIDER
- INVESTIGATOR
- OUTCOMES_ASSESSOR

Enrollment Info:
Count: 336
Type: ACTUAL

Arms Interventions Module

Arm Groups:
1.
Label: Immediate SSC and early breastfeeding during CS group

Type: EXPERIMENTAL
Description: Receiving immediate SSC and early breastfeeding during CS and routine newborn care
Intervention Names:
• Other: Immediate SSC and early breastfeeding during CS
• Other: Routine newborn care

2.
Label: control group
Type: OTHER
Description: Receiving delayed SSC and breastfeeding and routine newborn care
Intervention Names:
• Other: Delayed SSC and breastfeeding after CS
• Other: Routine newborn care

Interventions:

1.
Type: OTHER
Name: Immediate SSC and early breastfeeding during CS
Description: Upon birth, the neonate is promptly placed prone on the mother's chest, with their head turned to one side for optimal skin contact. The drying process begins within 5 seconds and is completed within 20 to 30 seconds while the neonate remains on the mother's chest. Delayed cord clamping is practiced, with the cord clamped approximately 1-3 minutes after birth. Breastfeeding cues such as tongue movements or head turning are monitored, and the obstetric nurse assists the mother in initiating breastfeeding as soon as possible. SSC continues throughout the cesarean procedure, and upon completion, the newborn is temporarily separated from the mother for safety during transfer to the surgical cart. SSC is resumed immediately post-transfer and continues for a cumulative duration of at least 90 minutes. The neonate's skin color, breathing, and feeding responses are continuously observed.
Arm Group Labels:
• Immediate SSC and early breastfeeding during CS group

2.
Type: OTHER
Name: Delayed SSC and breastfeeding after CS
Description: The neonate is dried within 20-30 seconds after birth, the cord is clamped after 1-3 minutes, and then the neonate is sent to the ward to wait for the mother to complete the surgery. Immediate SSC is initiated within one hour after birth and maintained with the mother for at least 90 minutes post-surgery, during which the neonate's skin color and breathing are continuously monitored. The obstetric nurse supports the mother in initiating breastfeeding at the earliest opportunity.
Arm Group Labels:
• control group

3.
Type: OTHER
Name: Routine newborn care
Description: Newborn eye care, vitamin K1 administration, immunizations, weighing, and standard examinations are conducted before the neonate is transferred to the ward.
Arm Group Labels:
• Immediate SSC and early breastfeeding during CS group
• control group

Outcomes Module

Primary Outcomes:

1.
Measure: Incidence of neonatal hypoglycemia
Description: Neonatal blood glucose levels were assessed using the Stat Strip Xpress glucose meter at 1, 3, and 6 hours after birth. Hypoglycemia was categorized as follows: mild hypoglycemia (overall) at \<45 mg/dL, moderate-to-severe at \<36 mg/dL, and severe at \<18 mg/dL. Treatment was initiated if levels dropped below 25 mg/dL or if symptoms like shakiness, tachycardia, pallor, hypothermia, hunger, sweating, or weakness appeared. In such cases, 10 ml/kg of formula was administered, followed by a recheck after 0.5 hour. If levels rise above 40

mg/dL, subsequent checks occurred every 3 hours. Persistent levels below 50 mg/dL necessitated continued formula feeding and monitoring, or transferred to neonatal care if needed.

Time Frame: 1, 3, and 6 hours after birth

Secondary Outcomes:

1.

Measure: Breastfeeding initiation time

Description: Characterized by newborns correctly latching onto the nipple and areola, and establishing regular, effective sucking and swallowing.

Time Frame: Assessment occurs immediately post-operation, with timing recorded to the minute.

2.

Measure: Duration of first breastfeeding

Description: Start Timing at Latch-On: Begin timing when the infant first latches onto the breast.

End Timing at Detachment: Stop timing when the infant detaches from the breast, either naturally or with assistance from the mother or healthcare provider.

Time Frame: Assessment occurs immediately post-operation, with timing recorded to the minute.

3.

Measure: Onset of lactogenesis II

Description: Marked by significant milk secretion perceived by the mother as breast fullness, confirmed by observing and squeezing the areola to assess milk spillage.

Time Frame: The assessment occurs from surgery to pre-discharge, with timing recorded to the hour postpartum, an average of 72 hours.

4.

Measure: Exclusive breastfeeding rate during hospitalization

Description: This rate was calculated for mothers who underwent cesarean delivery in both study groups.

Time Frame: The assessment occurs from delivery to pre-discharge, an average of 5 days.

Eligibility Module

Eligibility Criteria: Inclusion Criteria:

* mothers aged 18 years or older with a singleton pregnancy, gestational age between 34+1 and 41+6 weeks.
* undergoing elective cesarean section with epidural, subarachnoid block, or combined spinal-epidural anesthesia, willing to engage in mother-infant SSC during and after the surgery, without experiencing severe reactions to anesthesia like vomiting or shivering that could affect SSC.
* having intention to breastfeed with no major contraindications (e.g., hepatitis B, syphilis, HIV, or other infectious diseases).
* newborns with Apgar scores above 8 at 1 and 5 minutes, a strong sucking reflex, and no critical neonatal conditions requiring transfer.

Exclusion Criteria:

* serious pregnancy complications such as placenta previa, placenta accreta spectrum, eclampsia, and grade 3 or higher cardiac issues per NYHA standards.
* challenges in initiating mother-infant SSC include emergencies such as neonatal asphyxia or respiratory distress, maternal excessive bleeding during surgery, and maternal infectious dermatoses.
* previous breast surgeries such as biopsies or augmentations, nipple inversions complicating breastfeeding, or taking medications affecting lactation.

Healthy Volunteers: true

Sex: ALL

Minimum Age: 18 Years

Std Ages:

- ADULT
- OLDER_ADULT

Contacts Locations Module

Overall Officials:
1.
Name: Jia Qiao
Affiliation: Qingdao Municipal Hospital
Role: PRINCIPAL_INVESTIGATOR
Locations:
1.
Facility: Qingdao Municipal Hospital
City: Qingdao
State: Shandong
Zip: 266000
Country: China
Geo Point:
Lat: 36.06488
Lon: 120.38042
References Module

References:
1.
Pmid: 30930716
Type: BACKGROUND
Citation: Cuschieri S. The CONSORT statement. Saudi J Anaesth. 2019 Apr;13(Suppl 1):S27-S30. doi: 10.4103/sja.SJA_559_18.
2.
Pmid: 35986372
Type: BACKGROUND
Citation: Wang X, Zhang X, Sobel HL, Li Z, Juan J, Yang H. Early essential newborn care for cesarean section newborns in China: study protocol for a multi-centered randomized controlled trial. Trials. 2022 Aug 19;23(1):696. doi: 10.1186/s13063-022-06615-z.
3.
Pmid: 37361517
Type: BACKGROUND
Citation: Roeper M, Hoermann H, Kummer S, Meissner T. Neonatal hypoglycemia: lack of evidence for a safe management. Front Endocrinol (Lausanne). 2023 Jun 8;14:1179102. doi: 10.3389/fendo.2023.1179102. eCollection 2023.
Ipd Sharing Statement Module

Ipd Sharing: NO
Description: The paper needs to be submitted and published on a subscription basis, which has a longer cycle. Additionally, the data needs to be used for another paper, making it inconvenient to share.
DOCUMENT SECTION
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Large Document Module

Large Docs:
1.
Type Abbrev: Prot
Has Protocol: true
Has Sap: false
Has Icf: false
Label: Study Protocol

Date: 2022-06-01
Upload Date: 2024-08-03T08:07
Filename: Prot_000.pdf
Size: 213823

DERIVED SECTION
==========

Misc Info Module

Version Holder: 2025-06-26

Condition Browse Module

Meshes:
1.
Id: D007003
Term: Hypoglycemia

Ancestors:
1.
Id: D044882
Term: Glucose Metabolism Disorders
2.
Id: D008659
Term: Metabolic Diseases

Browse Leaves:
1.
Id: M25869
Name: Premature Birth
Relevance: LOW
2.
Id: M10053
Name: Hypoglycemia
As Found: Hypoglycemia
Relevance: HIGH
3.
Id: M11639
Name: Metabolic Diseases
Relevance: LOW
4.
Id: M25403
Name: Glucose Metabolism Disorders
Relevance: LOW

Browse Branches:
1.
Abbrev: BXS
Name: Urinary Tract, Sexual Organs, and Pregnancy Conditions
2.
Abbrev: All
Name: All Conditions
3.
Abbrev: BC18
Name: Nutritional and Metabolic Diseases

Intervention Browse Module

Browse Leaves:
1.
Id: M17558
Name: Vitamins
Relevance: LOW
2.
Id: M17555
Name: Vitamin K
Relevance: LOW
3.
Id: M13732
Name: Vitamin K 1
Relevance: LOW
4.
Id: T481
Name: Vitamin K
Relevance: LOW
5.
Id: T449
Name: Menadione
Relevance: LOW
6.
Id: T450
Name: Menaquinone
Relevance: LOW
7.
Id: T452
Name: Naphthoquinone
Relevance: LOW
8.
Id: T458
Name: Phylloquinone
Relevance: LOW
Browse Branches:
1.
Abbrev: Micro
Name: Micronutrients
2.
Abbrev: All
Name: All Drugs and Chemicals
3.
Abbrev: Coag
Name: Coagulants
4.
Abbrev: Vi
Name: Vitamins
HAS RESULTS
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