Research Square

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Oral Dextrose Gel vs Standard Care for the Treatment of Hypoglycemia in High-Risk Neonates: An Open-Label Randomized Controlled Trial

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Abstract

Purpose: To determine whether 40% dextrose gel with oral feeds reduces NICU admission for asymptomatic hypoglycemia compared with standard care with oral feeds in at-risk neonates within 48 hours of life.

Methods: Open-label randomized controlled trial conducted at a tertiary hospital in South India between April 2023 and May 2024. Neonates born at ≥35 weeks of gestation and identified with asymptomatic hypoglycemia within the first 48 hours of life were enrolled and randomly assigned to receive either 200 mg/kg of oral 40% dextrose gel, along with oral feeds, or standard care with oral feeds alone.

Results: A total of 193 neonates were enrolled, with 98 in the standard care group and 95 in the gel group. Baseline characteristics were comparable. NICU admission due to hypoglycemia was lower in gel group (4.2%) versus the standard care group (12.2%), with a relative risk of 0.34 (95% CI: 0.11–1.03), p = 0.06, and a number needed to treat (NNT) of 13. Exclusive breastfeeding at discharge was higher in the gel group (97 % vs. 76%), and this difference persisted at six weeks (90% vs. 69%). The incidence of rebound, recurrent hypoglycemia, and hyperglycemia was similar in both groups.

Conclusion: Oral dextrose gel reduces NICU admissions among at-risk neonates with asymptomatic hypoglycemia; however, this association was not statistically significant. It also improves exclusive breastfeeding rates at both hospital discharge and at the six-week follow-up.

Trial registration: Clinical Trials Registry of India (CTRI/2023/02/050027)

1. Introduction

Neonatal hypoglycemia is a common preventable cause of adverse neurological sequelae and poor cognitive and neurodevelopmental outcomes [1–3] . It affects around 5-15% of healthy newborns [4,5], depending on several factors like gestational age, weight, associated maternal and neonatal co-morbidities, and birth-related conditions [6,7]. Prolonged or recurrent asymptomatic hypoglycemia can cause irreversible brain damage, resulting in cognitive deficits and developmental delays [8,9]. Behavioural issues like anxiety disorders and attention-deficit/hyperactivity disorder (ADHD) may develop during early childhood [2]. Research indicates asymptomatic hypoglycemia may be more common in resource-poor settings [10]. Patients with persistent hypoglycemia receive intravenous glucose fluids in neonatal units, causing mother-baby separation and delayed breastfeeding establishment [11,12]. Further research is warranted in low and middle-income countries among at-risk neonates with asymptomatic hypoglycemia, to reduce Neonatal Intensive Care Unit (NICU) admissions and hence mother-baby separation [11,12]. Moreover, while previous quality improvement initiatives have explored feeding pathways to reduce hypoglycemia incidence, few randomized controlled trials have evaluated interventions that directly minimize NICU admissions in low-resource settings. Addressing this gap is crucial for scalable neonatal care models in developing countries.

Forty percent dextrose gel is widely used in developed countries for the prevention and treatment of hypoglycemia [12–15] . However, its effectiveness in developing countries remains uncertain. The gel's ease of administration makes it suitable for resource-limited settings as a first-line treatment before referral to higher centers. The primary objective was to assess whether oral dextrose gel reduced the need for NICU admission, a pragmatic and clinically meaningful outcome reflective of systemic burden, rather than solely biochemical normalization. Secondary objectives were to identify hypoglycemic or hyperglycemic episodes after gel administration versus standard care and evaluate feeding patterns at discharge and at six weeks.

2. Materials and methods

Study Design and Setting:

This open-label randomized controlled trial was conducted from April 2023 to May 2024 at a tertiary care hospital in South India. The Institutional Ethics Committee approved the study (IEC 220/2022) in accordance with the Declaration of Helsinki. The trial was registered with the Clinical Trials Registry of India (CTRI/2023/02/050027). The study involved at-risk healthy neonates born at ≥35 weeks' gestation with asymptomatic hypoglycemia, defined as blood glucose levels <50 mg/dL (<2.8 mmol/L) within the first 48 hours of life [16,17]. Neonatal risk factors included small for gestational age (SGA) with birth weight below the 10th percentile, low birth weight <2500 grams, large for gestational age (LGA) with birth weight above the 90th percentile or over 4000 grams, intrauterine growth restriction (IUGR), late preterm neonates ($35^{1/7}$-$36^{6/7}$ weeks), infant of diabetic mother (IDM) and discordant twins with a weight difference of at least 20%. Maternal pre-eclampsia and use of beta-blockers for hypertension in late pregnancy were the other risk factors. Neonates with perinatal asphyxia, suspected early-onset sepsis, chromosomal disorders, major congenital malformations needing ICU care, surgical conditions requiring intervention, or congenital infections were excluded.

Sample size:

Sample size calculation was based on an expected NICU admission rate of 40% among at-risk neonates and an anticipated absolute risk reduction of 20% (50% relative reduction), with α=0.05 and 80% power. This assumption was based on previous randomized trials showing substantial reductions in treatment failure with oral dextrose gel and on our retrospective unit data indicating a baseline NICU admission rate of 40% [13]. Considering a 5% dropout rate, the final sample size was estimated at 91 per group.

Screening and Glucose Monitoring:

Mothers having risk factors contributing to neonatal hypoglycemia were screened prenatally for eligibility, and informed consent was obtained from parents either before birth or immediately after delivery. Skin-to-skin care with breastfeeding was initiated shortly after birth. Eligible neonates born at

>35 weeks' gestation underwent random capillary blood glucose (RBS) testing after the first feed by heel prick at 1 hour of life using a point-of-care glucometer (iSens's NoCoding1 Plus), which was calibrated daily. Subsequent pre-feed RBS measurements were done at 2, 4, and 6 hours, then every 6 hours until 48 hours of life as per the protocol. Monitoring was stopped if two consecutive readings exceeded 65 mg/dL (3.6 mmol/L). For RBS <60 mg/dL (3.3 mmol/L), a capillary gas analysis was performed. Neonates with RBS <25 mg/dL (1.4 mmol/L) or showing symptoms were admitted to NICU for IV glucose therapy.

Randomization and Blinding:

Eligible neonates with asymptomatic hypoglycemia (RBS 25–50 mg/dL) were randomized using a computer-generated random number table with 1:1 allocation concealed by serially numbered opaque sealed envelopes (SNOSE technique). Randomization was stratified by gestational diabetes and by weight relative to gestational age, with block sizes of 4, 6, and 8. Twins were randomized independently. While participants and care providers were aware of group assignments due to the nature of the intervention, outcome assessors remained blinded. Feeding adequacy and exclusive breastfeeding status were assessed by trained lactation nurses who were not involved in group allocation.

Intervention:

The study procedure is shown in Fig. 1. ***Neonates in the Dextrose Gel Group*** received 40% dextrose gel (200 mg/kg, 0.5 mL/kg) [12] as an adjunct to oral feeds. The dextrose gel was supplied in single-use tubes. The calculated dose (0.5 mL/kg) was drawn into a syringe and administered to the buccal mucosa as an adjunct to oral feeds. Blood glucose was reassessed one hour after administration. Up to six doses were allowed over 48 hours, with a maximum of four doses in 24 hours. In the ***Standard Care Group*****,** oral feeds were continued, and RBS was rechecked after 1 hour. If lactation was inadequate, as assessed by lactation nurses, formula feeds (5–10 mL/kg) were given in both groups in addition to breastfeeding using a paladai (a traditional Indian spoon-like feeder used for neonates unable to suck directly). Breastfeeding adequacy was evaluated based on maternal milk production, the baby passing urine 5-6 times daily, and adequate passage of stools. Glucose monitoring was continued in both groups as per protocol.

Outcome Measures:

Admission to the NICU was considered if the neonate exhibited symptoms at any point in time in either group or if the neonate required three consecutive gel doses or four doses within a 24-hour period, or if blood glucose levels fell below 25 mg/dL at any time following gel or oral feeding. The procedure is detailed in Fig. 1. Treatment failure was defined as the need for NICU admission for hypoglycemia within the first 48 hours after the intervention. Rebound hypoglycemia was defined as hypoglycemia (RBS <50mg/dL) occurring within 1 hour of the intervention and requiring a repeat dose of gel or oral feed. Recurrent hypoglycemia was defined as hypoglycemia (RBS<50mg/dL) anytime during the first 48 hours of life after the intervention, requiring a repeat dose of gel or oral feed.

The primary outcome was the incidence of treatment failure needing NICU admission for hypoglycemia. Secondary outcomes included the number of rebound hypoglycemic episodes after intervention, the incidence of recurrent hypoglycemia or hyperglycemia post-intervention, and exclusive breastfeeding at discharge and six weeks.

Follow-up and Safety Monitoring:

Nurses and residents received training about the study procedure, dextrose gel administration, and feeding assistance. Baseline characteristics, primary, and secondary outcomes were collected during the hospital stay. All infants were followed up in the neonatal outpatient clinic at 6 weeks as part of the unit's standard protocol. Feeding pattern (exclusive breastfeeding, formula, or combined) and the baby's weight were recorded during follow-up. Follow-up outcomes were recorded during outpatient visits by a separate clinical team. The data monitoring and safety committee monitored for any adverse events.

Statistical Analysis:

Data were coded and recorded in an Excel spreadsheet and analyzed using Jamovi (Version 2.5.4) [18]. Statistical analyses were performed on an intention-to-treat basis. Descriptive data were summarized using mean (standard deviation) and median (Interquartile range, IQR) for parametric and nonparametric variables, respectively. Frequencies and percentages were used for categorical variables. The primary outcome was analyzed using the Chi-Square test. Fisher's exact test was used if the singular cell value <5. Secondary outcomes were analyzed using an Independent sample t-test for parametric data, Mann-Whitney U-test for non-parametric data, and a chi-square test for categorical outcomes. Relative risk or mean difference with 95% Confidence interval (CI) was provided for the primary and secondary outcome measures, and the number needed to treat (NNT) for the primary outcome was calculated. Multivariable logistic regression analysis was additionally performed to adjust for baseline confounders (late preterm, small for gestation, maternal diabetes) for the primary outcome. Statistical significance was taken as $p<0.05$. Interim analyses were performed when 50% of recruitment was completed.

3. Results

Of 856 screened neonates, 25 declined, and 41 were transferred to NICU for other reasons (Figure 2). Among the remaining 790 neonates, 193 had asymptomatic hypoglycemia and were randomized: 95 to the dextrose gel group and 98 to the standard care group. Baseline neonatal and maternal demographics were similar between the two groups (Table 1). All neonates had APGAR scores above seven at 5 minutes, with a median recruitment time of 2 hours for both groups. In the dextrose gel group, 87 neonates required one dose, 4 needed two doses, 3 needed three doses, and one neonate required four doses. Details of NICU admission (treatment failure) in the two groups are shown in Table 2. In dextrose gel group, four infants (4.2%) were admitted to NICU, versus 12 infants (12.2%) in standard care group, with a relative risk (RR) of 0.34 (95% CI: 0.11–1.03) and a p-value of 0.06. This represented a clinically important reduction in NICU admissions, although it did not reach conventional statistical significance. This indicates a 66% relative risk reduction in NICU admissions with gel treatment and an 8% absolute

reduction. The number needed to treat (NNT) to prevent NICU admissions (treatment failure) was 13, meaning for every 13 infants treated with dextrose gel versus standard care, one NICU admission was prevented. In multivariable logistic regression, adjusting for SGA, maternal diabetes, and late prematurity, infants in the Gel group had lower odds of NICU admission than those in standard care (OR 0.32, 95% CI 0.10–1.05, p = 0.06), although this did not reach conventional statistical significance. SGA infants had significantly higher odds of NICU admission (OR 4.06, 95% CI 1.28–12.83, p = 0.02). Maternal diabetes and late prematurity were not significantly associated with NICU admissions.

Table 3 highlights secondary outcomes, showing that no infants in the dextrose gel group experienced rebound hypoglycemia 1 hour after gel administration, compared with 2 (2.1%) in the standard care group, though this difference is not statistically significant (p = 0.49). The incidence of rebound, recurrent hypoglycemia, and hyperglycemia was not significantly different between groups. Blood glucose levels increased more in the dextrose gel group (median: 27) compared to the standard care group (median: 21), with a median difference of +6 mg/dL (p = 0.01). The dextrose gel group required significantly fewer formula feeds (median: 0) than the standard care group (median: 1), with a mean difference of -1 (p < 0.001). Neonates discharged on exclusive breastfeeding were higher in the dextrose gel group (97 %) than the standard care group (76 %) (RR: 1.28, p < 0.001), showing a 28% relative increase in exclusive breastfeeding at discharge and an absolute increase of 20%. At 6 weeks, exclusive breastfeeding remained 32% higher in the dextrose gel group (90%) versus the standard care group (69%) (RR: 1.32, p < 0.001).

4. Discussion

Our study suggests that in at-risk neonates with asymptomatic hypoglycemia, dextrose gel is associated with a clinically important reduction in NICU admissions compared with standard care in resource-limited settings. Although the primary outcome narrowly missed statistical significance, the large effect size, favourable NNT of 13, and consistency with adjusted analysis support its clinical relevance. The reduced NICU admission rate highlights the gel's effectiveness in stabilizing blood glucose levels early, thereby preventing the progression to severe hypoglycemia requiring intensive care. These findings are significant in neonatal care, where reducing NICU admissions alleviates the burden on healthcare systems and reduces the risks associated with prolonged NICU stays for families. Choosing NICU admission as the primary outcome, rather than biochemical normalization, reflects an emphasis on clinically significant benefits, particularly in low and middle-income countries (LMICs) where NICU resources are limited. Moreover, the higher exclusive breastfeeding rate in the dextrose gel group underscores its role in promoting maternal-infant bonding and supporting breastfeeding practices. These findings differ from previous quality improvement (QI) projects, which focused primarily on feeding support without formal randomization or objective clinical outcomes like NICU admission. The gel's ease of use and minimal interference with feeding may reduce the need for formula supplementation and optimize early breastfeeding.

The Sugar Babies trial, a randomized, double-blind, placebo-controlled study of neonates > 35 weeks' gestation and < 48 hours old, assessed treatment failure (blood glucose concentration of less than 2.6 mmol/L after two treatment attempts with dextrose gel or placebo) as the primary outcome. Dextrose gel had 14% treatment failure compared with 24% in placebo and RR 0·57 (95% CI 0·33–0·98; p=0·04) however rates of NICU admission were the same in both groups (RR 0.83, *p* = 0.24), but there were fewer admissions for hypoglycemia in the treatment group (RR 0.54, *p* = 0.03) [13]. The Hypoglycemia Prevention with Oral Dextrose Trial, a multicenter, double-blind, randomized controlled trial, included neonates at risk of hypoglycemia not requiring immediate NICU admission [12]. It found that neonates receiving dextrose gel were less likely to become hypoglycemic (37% vs. 42%) compared to the placebo group, with an RR of 0.87 (95% CI: 0.78-0.97). However, NICU admissions for hypoglycemia were similar between groups (6.1% for dextrose gel vs. 4.5% for placebo), indicating no significant difference in NICU admission rates. The first randomized trial with glucose gel in the Indian subcontinent by Gupta et al. showed a significant reduction in treatment failure rates in the dextrose gel group (11.5%) compared to the control group (40.2%), with a relative risk (RR) of 0.28 [17]. Similarly, our study showed a 66% reduction in NICU admissions in the dextrose gel group (4.2%) compared to the Control (standard care) group (12.2%), with a relative risk (RR) of 0.34 (95% CI: 0.11-1.03). Our findings also revealed that the dextrose gel group required fewer IV fluids (3.2%) than the standard care group (9.2%), though this difference was not statistically significant (p=0.08), suggesting that dextrose gel helps minimize the need for invasive treatments.

Our study adds value by being the first in South Asia to prioritize NICU admission as a primary clinical outcome rather than just biochemical resolution or feeding success. Several factors support the practical relevance of our findings. First, the effect size is large (RR 0.34) with an NNT of 13, indicating that one NICU admission may be averted for every thirteen infants treated. Second, the 95% CI excludes harm and is compatible with a meaningful benefit, while the study was underpowered because the observed event rate was lower than anticipated. Third, the adjusted model showed concordant benefit (aOR 0.32; 95% CI 0.10–1.05; p=0.06). Additionally, the dextrose gel group had higher exclusive breastfeeding rates at discharge (96.8% vs. 75.5%), suggesting better health outcomes and enhanced mother-infant bonding. Furthermore, the higher breastfeeding rates and reduced NICU admissions in our study reflect the practical advantages of dextrose gel in managing neonatal hypoglycemia more effectively and non-invasively. This is in line with most studies done in developed nations [12–15,19]. Our results add to existing evidence by providing interventional trial data from a low-resource setting, where management practices and breastfeeding support differ significantly from high-income countries. Our study results concur with the latest Cochrane reviews on dextrose gel for neonatal hypoglycemia but differ in outcomes across various contexts [16, 20].

Exclusive breastfeeding practices differ among developed nations due to public health policies, cultural practices, maternity leave provisions, and breastfeeding support. The global average is 48% as per UNICEF, Global Breastfeeding Scorecard 2023 [21] while in our study, baseline breastfeeding rates were higher in both groups and improved at discharge and at 6 weeks in the intervention group. Our research shows dextrose gel is effective for managing neonatal hypoglycemia even in settings with higher

exclusive breastfeeding rates. Besides reducing NICU admissions, increasing exclusive breastfeeding rates at six weeks may improve cognitive and developmental outcomes. Future research aimed at long-term neurodevelopmental outcomes is required. Moreover, dextrose gel is an affordable option, costing approximately Rs. 150 per baby. It can be easily prepared in hospital pharmacies and stored at room temperature, making it highly useful in resource-limited settings where neonatal hypoglycemia is common.

Strengths of the study include a rigorous protocol and a low loss-to-follow-up rate of less than 10%, attributed to the robust sample size. The exclusive breastfeeding rate of 90% observed in the dextrose gel group at six weeks notably exceeded the national average of 64% as reported by NFHS-5 and surpassed international standards due to a strict breastfeeding policy and lactation support [22]. Though this study provides valuable insights, it has certain limitations. Firstly, blinding was not feasible due to the nature of the intervention; however, outcome assessments were blinded to minimize bias. While point-of-care glucometers were used for screening, values <60 mg/dL were verified by capillary gas analysis to minimize false positives. However, the absence of continuous glucose monitoring (CGM) may have led to underdetection of brief hypoglycemic episodes; future studies incorporating CGM are recommended. The actual incidence of hypoglycemia in both groups was lower than the expected risk, which may reflect better early feeding practices in the study population, limiting generalizability to settings with different breastfeeding support systems.

In conclusion, this randomized controlled trial adds important evidence from a low-resource setting. Oral dextrose gel was associated with fewer NICU admissions and higher exclusive breastfeeding rates without safety concerns. While the primary outcome did not achieve statistical significance, the direction and magnitude of effect, consistency with adjusted analyses, and favourable number needed to treat suggest meaningful clinical benefit. What this study adds is that even in settings with already high breastfeeding support, dextrose gel remains a simple, safe and low cost intervention that can reduce the need for NICU admission and support breastfeeding outcomes. Larger, adequately powered multicenter trials are warranted to confirm these findings and assess long-term benefits.

Declarations

Author Contributions:

1. Substantial contributions to the study concept, design of the work, data acquisition, analysis, and interpretation of data for the work: SB, SKB, LL.
2. Drafting the work, reviewing it critically for important intellectual content, and final approval: SB, SKB, LL, SM, JP
3. Funding acquisition: SB, SKB, LL

All the authors reviewed the manuscript and gave final approval of the version to be published.

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Conflict of Interest: The authors declare no conflicts of interest.

Trial Registration: Clinical Trials Registry of India (CTRI): CTRI/2023/02/050027

Ethical Approval: Ethical approval was obtained from the Institutional Ethics Committee, Kasturba Medical College, Manipal (IEC Project No. 220/2022, approved 9 January 2023) in accordance with the Declaration of Helsinki.

Consent to Participate

Written informed consent was obtained from parents before enrolment.

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Tables

Tables 1 to 3 are available in the supplementary files section

Figures

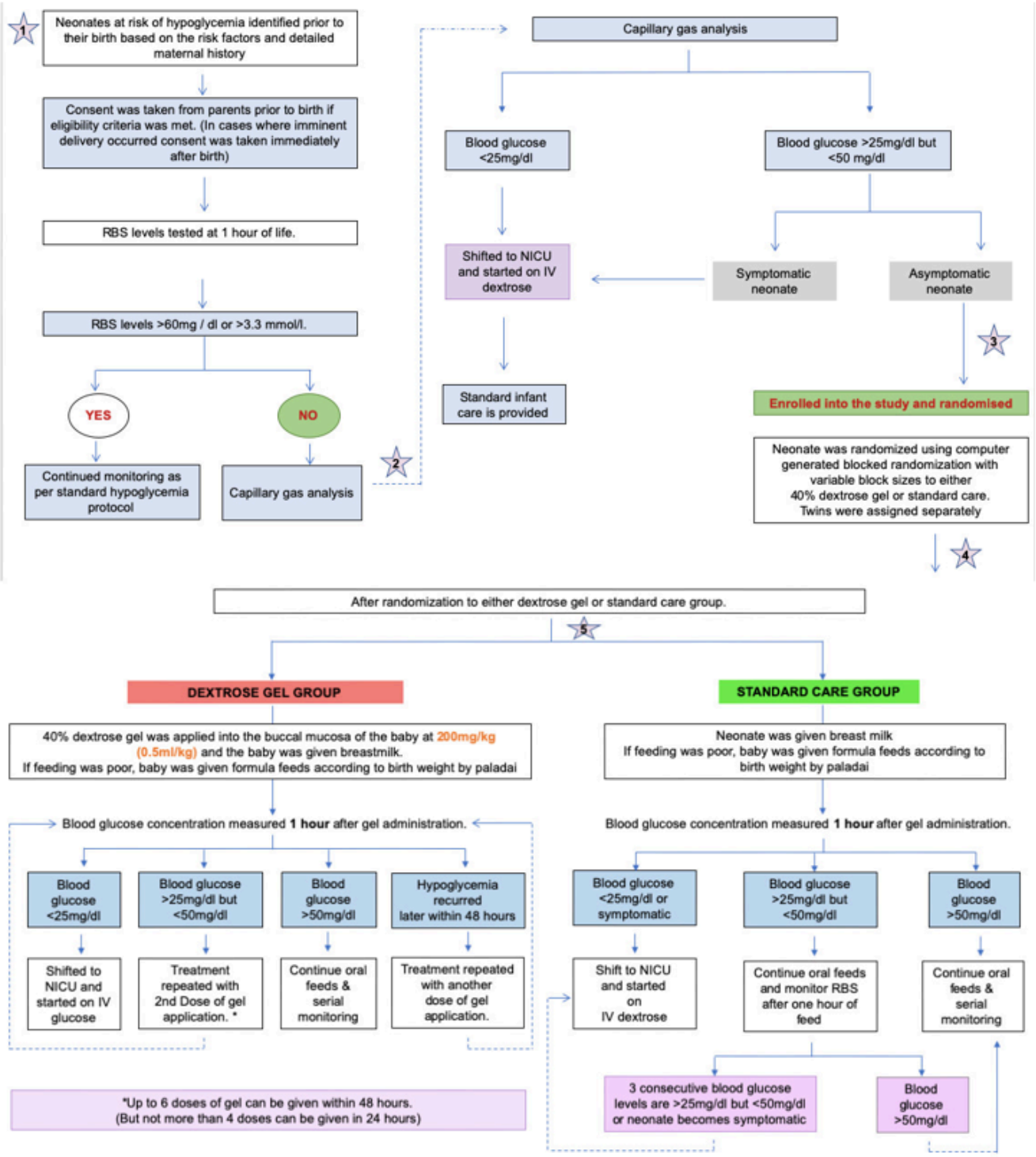


Figure 1

Study protocol outlining the sequential flow of participant identification, eligibility screening, randomization, intervention (oral dextrose gel or standard care), blood glucose monitoring, and criteria for NICU admission or treatment continuation. The numbers 1-5 represent the ordered clinical steps in the protocol.

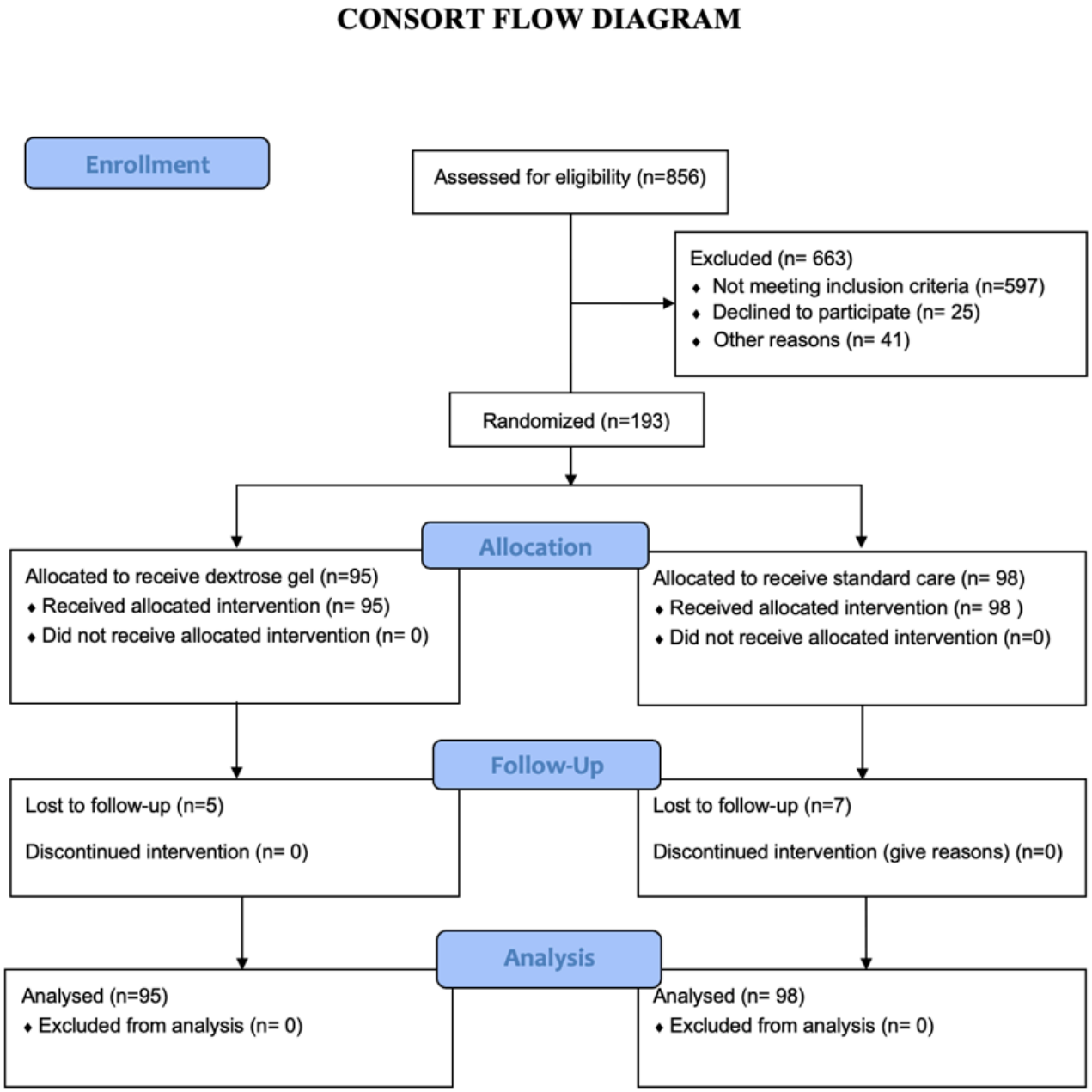


Figure 2

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