Register No : 4724
Received Date : 10/08/25
Meeting Date : 15/08/25
Approved : 23/08/25

Bangabandhu Sheikh Mujib Medical University
Shahbagh, Dhaka -1000

Application for Institutional Review Board (I.R.B) Clearance

Title of the study : Efficacy of delivery room bubble continuous positive airway pressure in preterm neonates <34 weeks having respiratory distress

Principal Investigator : Dr. Nuzhat Nuary Jui

1. Name of present course : MD-Neonatology
2. Joining date in thesis part : March, 2025
3. Name of Institute : Bangabandhu Sheikh Mujib Medical University
4. Expected Date of Examination : November, 2026
5. Guide : Asso. Prof. Dr. Sadeka Choudhury Moni
   Associate Professor,
   Department of Neonatology, BSMMU.
6. Place of the Study : Department of Neonatology, BSMMU.

8.Type of the study : Randomized controlled trial
9.Duration : 1 Year
10.Total cost : 2,82,980
11.Funding Agency (lf Applicable) : Self

We agree to obtain approval of the Institutional Review Board of BSMMU for any changes involving the rights and welfare of subjects or any changes of the Methodology before making any such changes.

Principal Investigator **Guide:**

Dr. Nuzhat Nuary Jui
Resident, MD (Phase - B)
Department of Neonatology
BSMMU, Shahbag, Dhaka.

Asso. Prof. Dr. Sadeka Choudhury Moni
Associate Professor
Department of Neonatology
BSMMU, Shahbag,

Application to the Chairman

Date : 10/08/25

To

The Chairman

Department of Neonatology

Bangabandhu Sheikh Mujib Medical University (BSMMU)

Shahbagh, Dhaka

Subject: Permission for conducting a research work

Sir,

Assalamu alaikum, I would like to conduct a research work titled 'Efficacy of delivery room bubble continuous positive airway pressure in preterm neonates <34 weeks having respiratory distress' over a period of 1 (one) years in the department of Neonatology.

It would be my privilege if you kindly allow me to conduct the research work in your department for the above mentioned period.

Sincerely yours

Dr. Nuzhat Nuary Jui
Resident
Department of Neonatology
Bangabandhu Sheikh Mujib Medical University
Shahbagh, Dhaka.

To

The Chairman
Institutional Review Board (IRB) and Pro- VC (Academic)
Bangabandhu Sheikh Mujib Medical University (BSMMU)
Shahbagh, Dhaka - 1000.

Subject: Submission of a Research proposal for IRB clearance

Dear Sir,

Dr. Nuzhat Nuary Jui, working as a resident, Department of Neonatology of BSMMU, submitted a research proposal titled '**Efficacy of delivery room bubble continuous positive airway pressure in preterm neonates <34 weeks having respiratory distress** to obtain IRB clearance**.**

I am forwarding this research proposal for your kind perusal and necessary action.

Thanking you,

Professor Dr. Sanjoy Kumer dey
Chairman
Department of Neonatology
Bangabandhu Sheikh Mujib Medical University
Shahbagh, Dhaka- 1000, Bangladesh.

Put Tick sign (√) appropriate answers against each of the following statement
(If not Applicable, Please write NA)

1. Source of Population:

(a) Patients	[√] Yes	[ ] No
(b) Healthy Subjects	[ ] Yes	[√] No
(c) Minors or person under guardianship	[√] Yes	[ ] No

2. Does the study involve:

(a) Physical risks to the subjects	[ ] Yes	[√] No
(b) Social Risks	[ ] Yes	[√] No
(c) Psychological risks	[ ] Yes	[√] No
(d) Discomfort to subjects	[ ] Yes	[√] No
(e) Invasion of the body	[ ] Yes	[√] No
(f) Invasion of Privacy	[ ] Yes	[√] No
(g) Disclosure of information damaging to subject or others	[ ] Yes	[√] No

3. Does the study involve

(a) Use of records:- (Hospital, Medical, Death, Birth or other)	[√] Yes	[ ] No
(b) Use of foetal tissues or Abortus	[ ] Yes	[√] No
(c) Use of organs body/fluid	[ ] Yes	[√] No

4. Are subjects clearly informed about:

(a) Nature and purposes of Study	[√] Yes	[ ] No
(b) Procedures to be followed including alternative used	[√] Yes	[ ] No
(c) Physical risks	[√] Yes	[ ] No
(d) Private questions	[√] Yes	[ ] No
(e) Mental risks	[√] Yes	[ ] No
(f) Benefits to be derived	[√] Yes	[ ] No
(g) Right to refuse to participate or to withdraw from study	[√] Yes	[ ] No
(h) Confidential handling of data	[√] Yes	[ ] No
(i) Compensations: (where there are risks or loss of working time or privacy is involved in any particular procedure)	[ ] Yes	[√] No

5.Signed consent form will be obtained:

(a) From Subjects (If adult)	[ ] Yes	[√] No
(b) From parent or guardian (if subjects are minor)	[√] Yes	[ ] No

6. Will precautions be taken to protect anonymity of subjects? [√] Yes [ ] No

Abstract for Institutional Review Board

Continuous Positive Airway Pressure (CPAP) is a well-established mode of respiratory support in preterm newborns. Early continuous positive airway pressure (CPAP) has proven to be beneficial in reducing ventilator dependence and subsequent chronic lung disease in neonates suffering from Respiratory distress.

In preterm infants, both immature development of the airways and chest and limited surfactant secretion result in a strong tendency to lung collapse with restriction of residual functional capacity. The use of continuous positive airway pressure (CPAP) has been pointed out as a suitable option to prevent loss of pulmonary volume and to minimize the use of mechanical ventilation and of surfactant. In theory, the earlier that CPAP applied, the lower the tendency for loss of residual functional capacity and the easier the respiratory stabilization of preterm infants.

Objective:

To evaluate the efficacy of delivery room bubble continuous positive airway pressure (CPAP) in reducing the incidence of respiratory morbidity and mortality in preterm neonate during the hospital stay in early neonatal period.

Methodology: This randomized controlled clinical trial will be conducted in Neonatal Intensive Care Unit (NICU) and Department of Obstetrics & Gynecology of Bangabandhu Sheikh Mujib Medical University, a tertiary care hospital of Dhaka city after approval by Institutional Review Board. The duration will be of one and half year. Preterm neonate gestational age less than 34 weeks fulfilling the inclusion criteria will been enrolled in the study after getting informed consent from the parents. Proper maternal history & neonatal characteristics will be recorded in data collection form. Delivery room CPAP of the enrolled babies will be started as early as

possible within 10 minutes. Another group which is control group will be managed by supplemental O_2 in delivery room. Both group will be enrolled by block randomization. Then the both group will be transferred to NICU with respiratory support and managed according to institutional protocol. Statistical analyses will be performed using the Statistical Package for Social Sciences (SPSS), version 25.

Results: Results will be incorporated after the study.

Conclusion: The conclusion will be incorporated after the study.

Table of content

'Efficacy of delivery room bubble continuous positive airway pressure in preterm neonates <34 weeks having respiratory distress: a single center randomized controlled clinical trial '

Principal Investigator:

Dr. Nuzhat Nuary Jui

MD (Phase - B)

Department of Neonatology

BSMMU, Dhaka.

Guide:

Associate Professor Dr. Sadeka Choudhury Moni

Associate Professor

Department of Neonatology

Bangabandhu Sheikh Mujib Medical University

Shahbag, Dhaka- 1000, Bangladesh.

Title: 'Efficacy of delivery room bubble continuous positive airway pressure in preterm neonates <34 weeks having respiratory distress: a single center randomized controlled clinical trial'

Introduction

Continuous Positive Airway Pressure (CPAP) is a well-established mode of respiratory support in preterm newborns. Early continuous positive airway pressure (CPAP) has proven to be beneficial in reducing ventilator dependence and subsequent chronic lung disease in neonates suffering from Respiratory distress.

In an attempt to prevent the injuries caused by mechanical ventilation, there has been a search for less aggressive (non-invasive) ways of providing respiratory support for preterm neonates who require respiratory support. The recent evidence supports use of continuous positive airway pressure (CPAP) for management of respiratory distress in these preterm neonates. CPAP generates a continuous distending pressure in the alveoli throughout the respiratory cycle. It splints the airways, improves lung compliance, conserves surfactant and reduces work of breathing. It prevents the loss of pulmonary volume and minimizes the use of mechanical ventilation and surfactant.

bCPAP is a simple and cost effective respiratory support system (RSS) which consists of products that are easily available and health care provider can easily be trained to make and use this system.

Globally, an estimated 15 million children are born prematurely each year and this number is rising and most of them (96%) are in developing countries. (Blencowe et al. 2013) (WHO health statistics, 2018). Preterm birth and its complications are a leading cause of under-five mortality, causing more than one million deaths per year. In Bangladesh, 573,000 premature neonates born each year and 32 % of neonatal death occur from prematurity.

In preterm neonates, immature development of the airways and limited surfactant secretion result in a strong tendency to alveolar collapse with reduced functional

residual capacity. Many neonates born at <34 weeks gestation require respiratory support.

Earlier application of the CPAP is supposed to the fact that, the lower the tendency for loss of functional residual capacity and the easier the respiratory stabilization of these preterm neonates. Early CPAP may be beneficial in reducing ventilator dependence and subsequent chronic lung disease in the extremely low birth weight (ELBW) neonates.

Bubble CPAP (bCPAP) is the least expensive and least complicated CPAP option, making this the preferred technology in resource-limited settings. Early bubble CPAP reduced delivery room intubations, days on mechanical ventilation and postnatal steroid usage. It was associated with increased postnatal weight gain and no complications (Narendran et al 2013)

B-CPAP was effective in the treatment of neonates who were suffering from respiratory distress and reduced the duration of hospital stay. In addition to mentioned benefits, its low cost may be the reason to use B-CPAP broadly compared with V-CPAP. (Bahareh et al 2013)

Early nasal CPAP is an effective treatment of respiratory distress in very low birth weight neonates, significantly reducing the need for intubation and mechanical ventilation (Gittermann et al 2003)

Early vs late CPAP: The application of CPAP early in the course of the disease before alveolar collapse occurs may work better than late CPAP by reducing lung damage and promoting lung function and surfactant pool. In the systematic review that compared early CPAP (starting CPAP at the time of randomization) *vs.* late CPAP (initiating late in the course of disease when FiO2 requirement is > 0.60), early CPAP was associated with a significant reduction in subsequent use of mechanical

ventilation [RR 0.55, (95% CI 0.32, 0.96); NNT 6]. But early CPAP had no effect on overall mortality, bronchopulmonary dysplasia (BPD) or pneumothorax (GUPTA, *et al, 2015).*

Rationale of the study

In preterm infants, immature development of the airways and chest as well as limited surfactant secretion result in a strong tendency to lung collapse with restriction of residual functional capacity. In an attempt to prevent the injuries caused by mechanical ventilation, there has been a search for less aggressive ways of promoting respiratory support for these patients. The use of continuous positive airway pressure (CPAP) has been pointed out as a suitable option to prevent loss of pulmonary volume and to minimize the use of mechanical ventilation and of surfactant therapy. Again it is a simple, low-cost and effective alternative to improve the respiratory status of preterm infants with respiratory distress. Earlier application of CPAP is supposed to lower the tendency for loss of residual functional capacity and prevent atelectasis, so lesser pressure is required, which results in better gas exchange. Bubble CPAP is more cost effective, less intensive, requires less training and has lower risk of complications.

In our country, neonatal care is expanding day by day. Total 59 numbers of SCANU has been established. The ultimate goal of these study is to better understand the role of bCPAP in reducing respiratory distress in resource-limited settings. This will help to improve implementation of bCPAP and scale-up of this technology to reduce neonatal mortality and morbidity from respiratory illness.

Research question

Does the use of bubble continuous positive airway pressure (bCPAP) in the delivery room reduce the incidence of respiratory morbidity and mortality of preterm neonate during early neonatal period?

Hypothesis:

Delivery room bubble CPAP reduces the incidence of respiratory morbidity and mortality of preterm neonate during early neonatal period.

Objectives

General

To examine the efficacy of delivery room bCPAP in preterm neonates with respiratory distress.

Specific

- To observe frequency of mechanical ventilator and surfactant administration in delivery room bCPAP group.
- To observe frequency of mortality in early neonatal period in delivery room bCPAP group.
- To observe frequency of mechanical ventilator and surfactant administration in delivery room supplemental O_2 group.
- To observe frequency of mortality in early neonatal period in delivery room supplemental O_2 group.
- To compare the respiratory outcome of both group.

Materials and Methods

Study design

Randomized controlled clinical trial.

Place of study

- In the Department of Obstetrics & Gynecology, Bangabandhu Sheikh Mujib Medical University, Shahbagh, Dhaka, Bangladesh
- In the Department of Neonatology, Bangabandhu Sheikh Mujib Medical University, Shahbagh, Dhaka, Bangladesh.

Study period

One and half year from approval of Institutional Review Board.

Study population

Preterm neonate less than 34 weeks having respiratory distress after birth.

Selection of patients

Inclusion criteria:

- Neonate gestational age less than 34 weeks delivered at BSMMU.
- Having respiratory distress.
- Neonate whose parents give consent to be enrolled in these study.

Exclusion criteria:

- Congenital anomaly such as cleft lip, cleft palate, congenital diaphragmatic hernia.
- Newborn required delivery room intubation
- Multiple gestation.
- Neonate whose parents don’t give consent to be enrolled in these stud

Study variable

Dependent variable

- Respiratory severity score (Silverman score)
- Need for mechanical ventilation
- Need for surfactant
- Mortality within 7 days
- Frequency of Apnea

Independent variable

Antenatal factors

1. Maternal diseases e.g.-Diabetes mellitus, Hypertension etc
2. Antenatal corticosteroid.
3. Chorioamnionitis

Neonatal factors

1. Gestational age (weeks)
2. Birth weight (gram)
3. Sex(male/female)
4. APGAR Score at1^{st} and 5^{th}minute
5. Fetal growth at birth (SGA, AGA, LGA)
6. Perinatal asphyxia
7. Mode of resuscitation
8. Necrotizing enterocolitis
9. Length of hospital stay
10. Patent ductus arteriosus

Operational definition

Early Neonatal period: It is defined as period from birth to can be further 7 completed days of birth.

Gestational age: It is the time elapsed between the first day of the last menstrual period and the day of delivery. Gestational age is expressed in completed weeks (Gomella et al. 2013)

Preterm neonate: Less than 37 completed weeks (less than 259 days) of gestation (World Health Organization, 2011).

Birth weight is the first weight of the fetus or newborn obtained after birth. For live births, birth weight should preferably be measured within the first hour of life before significant postnatal weight loss has occurred.

Respiratory Distress is defined as presence of any two of the following features such as respiratory distress more than 60 breath / min , subcostal / intercostal recession, expiratory grunting/groaning. (BSMMU protocol, AIMS protocol)

Appropriate for gestational age (AGA) is defined as a birth weight between 10th and 90th percentile for infant's gestational age.

Small for gestational age (SGA) is defined as a birth weight below 10th percentile for infant's gestational age.

Large for gestational age (LGA) is defined as a birth weight above 90th percentile for infant's gestational age.

APGAR score is a measure of the physical condition of a newborn infant. APGAR stands for appearance, pulse or heart rate, grimace, activity and respiration of the newborn after birth assessed at 1^{st} and 10^{th} min of life. It is obtained by adding points (2, 1 or 0) for these above-mentioned parameters. A score of 0-3 means mild respiratory distress, 4-7 moderate respiratory distress and >7 means severe respiratory distress (Gomella, 2020).

Multiple gestations occur when more than one fetuses carried during a pregnancy (Gomella, 2020).

Gestation diabetes mellitus (GDM) is defined as carbohydrate intolerance of variable severity first diagnosed during pregnancy (fasting blood sugar 7 mmol/L or above and 2 hours after 75g glucose 11.1 mmol/L or above (Gomella,2020).

Pregnancy induced hypertension (PIH) is manifested by hypertension (Blood pressure 140/90 mm Hg or more) without proteinuria after 20 weeks of gestation (Gomella, 2020).

Intra ventricular hemorrhage (IVH) is defined as ultrasonographic evidence of germinal matrix hemorrhage (Gomella, 2020).

Ethical consideration

There is a minimum physical, psychological, social and legal risk during taking history, physical examination, and investigations. Proper safety measures will be taken in every step of the study. The only researcher will be allowed to access the collected data. Ethical clearance will be obtained from the Institutional Review Board (IRB) of BSMMU to undertake the current study. According to Helsinki Declaration for Medical Research involving Human Subjects 1964, all the patients will be informed about the study design, the underlying hypothesis and the right of the participants to with draw themselves from the research at any time, for any reason. Informed written consent will be obtained from parents who will voluntarily provide consent to participate in this study.

The following ethical issues will be addressed accordingly:

- Strict confidentiality and security of data related to the patient will be maintained.
- The presentation of data and information related to the patient will be documented anonymously.
- The data analysis will be completed on the subjects who complete the study according to the protocol after recruitment of subjects with valid informed consent.
- There is no additional risk or safety concern due to the research process to either patient or researcher.
- There is no potential conflict of interest in this study and an entirely academic research project.

Study procedure

This randomized controlled clinical trial will be conducted over eighteen months period in the Department of Neonatology and Department of Obstetrics & Gynecology, BSMMU, Dhaka after approval by IRB. An informed consent in local language from parents will be taken prior to enrollment of their neonates. The study included all spontaneously breathing preterm neonates (<34 completed weeks of gestational age) with mild to moderate respiratory distress and neonates with critical congenital heart disease, congenital anomalies , congenital diaphragmatic hernia, newborn required delivery room intubation, multiple gestation will be excluded from the study. Preterm neonates fulfilling the inclusion criteria will be managed under radiant warmer and will be assessed for respiratory distress score and saturation will be monitored by attaching pulse oximeter. One group will be managed by initiated bubble CPAP and another group will be managed by supplemental O2. Respiratory support will be started within 10 minutes of birth. Selection will be done by block randomization.

Subsequently the both group of neonates will be transferred to neonatal intensive care with same respiratory support. Then both group will be managed by institutional protocol.

The primary outcomes will be evaluated whether they need surfactant therapy or mechanical ventilation or died in early neonatal period. The secondary outcomes to be evaluated are duration of CPAP, apnea and complication such as pneumothorax, patent ductus arteiosus and intra ventricular hemorrhage. These neonates will be compared to historical controls, matched for birth weight and gestational age.

Data will be collected daily for 7days during hospital stay.

Sample size calculation

$n_1 = \left(Z_{1-\alpha/2} + Z_{1-\beta}\right)^2 \frac{p_1(1-p_1)+p_2(1-p_2)}{(p_1-p_2)^2}$

Here,

n = estimated sample size

Proportion of Outcome of group 1 (p1) = 30 % (It is found out from previous study Saumil Ashvinkumar Desai, Pankaj Tule, Ruchi Nimish Nanavati, 2017)

Proportion of Outcome of group 2 (p2) = 67 % (It is found out from previous study Saumil Ashvinkumar Desai, Pankaj Tule, Ruchi Nimish Nanavati, 2017)

Level of significance (α) = 0.05

Power (1-β) = 0.80

Z alpha value =1.96

Z beta value = 0.84

$n_1 = (1.96 + 0.84)^2 \frac{0.3(1-0.3)+0.67(1-0.67)}{(0.30-0.67)^2}$

Sample size for group 1 (n1) = 25.3

Sample size for group 1 (n2) = 25.3

Attrition %= 20 %

So,

So estimated total sample size for this study is 60.

Statistical analysis

After collecting the data, it will be entered in a personal computer, then following steps will be used to analyze the collected data-

Statistical analyses will be performed using the Statistical Package for Social Sciences (SPSS), version 25. Continuous variables will be presented as mean ± SD for normally distributed data and as median (interquartile range) for skewed data. Categorical variables will be presented as frequencies and percentages. The unpaired Student *t* test will be used for quantitative variables with a normal distribution and the Mann-Whitney U test will be used for variables with a skewed distribution. The chi square test will be performed for qualitative variables. Result will be considered statistically significant if values of- $P<0.05$. Correlations between continuous variables will be performed by Pearson correlation coefficient (r). The predictive power of different variables will be assessed by receiver operating characteristic (ROC) curve. Logistic regression analysis will be used to test the association of variables with outcome.

Dummy tables

Table 1:Comparison of Maternal characteristics between delivery room group and control group

Parameter	Delivery room CPAP group	Control Group (n=30)	P-value
Maternal Age (years)			
Mode of delivery (%) NVD / cesarean			
Multiple gestation (%)			
Maternal hypertension (%)			
Eclampsia/ pre-eclampsia (%)			
Maternal diabetes (%)			
Chorioamnionitis (%)			
Oligohydramnios (%)			
Corticosteroid (%)			

Table2: Comparison of Neonatal characteristics between delivery room group and control group :

Parameters	Delivery room CPAP group	Control group	P value
Gestational age (wks.)			
Sex (male/female)			
Birth weight (gram)			
APGAR Score at 01 minute			
APGAR Score at 05 minute			
Mask ventilation in the delivery			
Intubation in the delivery room			

Table 3: Comparison of primary outcomes

Variable	Delivery room CPAP Group n (%)	Control Group n (%)	P value
Need for mechanical ventilation			
Need for surfactant			
Death within 7 days of hospital stay			

Table 4: Comparison of Secondary Outcomes

Outcome	Delivery room CPAP Group n (%)	Control Group n (%)	P value
Frequency of apnea			
Days receiving CPAP			
Days receiving oxygen treatment			
Days until full enteral feeding			
Complications (%)			
Pneumothorax			
Intraventricular hemorrhage			
Necrotizing enterocolitis			
Patent ductus arteriosus			

APPENDIX I

Data collection form

Title: '**Efficacy of delivery room continuous positive airway pressure in preterm neonates <34 weeks having respiratory distress: a single center randomized controlled clinical trial'**.

Principle investigator

Dr. Nuzhat Nuary Jui

Place of study

Department of Neonatology, BSMMU, Shahbagh, Dhaka

Date:

ID no:

A. Particulars of the patient:

Registration no: | | | | | | |

Date of admission: | | | | | | | | | | |

Name of the newborn:

Name of the mother:

Name of the father:

Date of birth: | | | | | | | | | |

Postnatal age on admission (minutes): | |

Address:

Contact detail: Mobile no. | | | | | | | | | | |

Land phone no. | | | | | | | | | |

Email address:

B. Maternal Information:

Maternal age (years): ☐☐

Gestation: ☐ Single Multiple ☐

Mode of Delivery ☐ Vaginal LUCS ☐

Hypertension: ☐ Yes No ☐

If yes: ☐ Duration (in months) Medication ☐

Preeclampsia / Eclampsia: Yes ☐ No ☐

If yes: History of taking $MgSO_4$ Yes ☐ No ☐

Oligohydramnios: Yes ☐ No ☐

Chorioamnionitis: Yes ☐ No ☐

Placental abnormality: Yes ☐ No ☐

Pre-gestational Diabetes mellitus: Yes ☐ No ☐

Gestational Diabetes mellitus: Yes ☐ No ☐

If yes: Controlled with Diet ☐ Insulin ☐

Antenatal Corticosteroid: Yes ☐ No ☐

C. Neonatal Information:

Gestational age (weeks): ☐

28-30 ☐ 31-32 ☐ 33- 34 ☐

Sex: ☐ Male ☐ Female

Birth weight (gram): ☐

< 1200 ☐ 1200-1500 ☐ > 1500 ☐

Small for gestational age: Yes ☐ No ☐

Intra-uterine growth retardation: Yes ☐ No ☐

If yes: Symmetrical ☐ Asymmetrical ☐

APGAR score at 1 minute < 7: Yes ☐ No ☐

APGAR score at 5 minutes <7: Yes ☐ No ☐

D. Clinical parameters of the patient:

Admitted to NICU: Yes ☐ No ☐

Prolonged Capillary refill time: Yes ☐ No ☐

Tachycardia: Yes ☐ No ☐

Bradycardia: Yes ☐ No ☐

Hypothermia: Yes ☐ No ☐

Respiratory distress: Yes ☐ No ☐

Sepsis: Yes ☐ No ☐

Seizure: Yes ☐ No ☐

Duration of hospital stay:

Hospital events:

Need for mechanical ventilation:	Yes ☐	No ☐
Need for surfactant:	Yes ☐	No ☐
Death within 7 days of hospital stay:	Yes ☐	No ☐
Frequency of apnea:	Yes ☐	No ☐
Days receiving CPAP:	☐	
Days until full enteral feeding	☐	

Complications:

Pneumothorax:	Yes ☐	No ☐
Intraventricular hemorrhage:	Yes ☐	No ☐
Necrotizing enterocolitis：	Yes ☐	No ☐
Patent ductus arteriosus：	Yes ☐	No ☐

Discharged on:

APPENDIX II

Informed Written Consent

Title: '**Efficacy of delivery room** bubble **continuous positive airway pressure in preterm neonates <34 weeks having respiratory distress: a single center randomized controlled clinical trial'**.

Investigator's name: Dr. Nuzhat Nuary Jui

Institution/organization: Bangabandhu Sheikh Mujib Medical University.

Purpose of this consent form is to inform you about necessary information that will help you for making decision to participate in this study.

Purpose of the study: To evaluate the efficacy of delivery room bubble continuous positive airway pressure (CPAP) in reducing the incidence of respiratory morbidity and mortality in preterm neonate during the hospital stay in early neonatal period.

Procedure: After birth, preterm neonate less than 34 weeks will be assessed for respiratory distress. Baby who will be enrolled randomized by block randomization in two group, one group will get CPAP another group will be managed by supplemental O2. Both the group will transferred to NICU and managed accordingly by institutional protocol. Both group will be assessed for need for primary outcome mechanical ventilation, surfactant administration and death within 7 days and secondary outcome frequency of apnea, duration of CPAP, complication like pneumothorax, intraventricular hemorrhage.

Risks: Baby will not be exposed to any physical risk.

Right to withdraw: Your baby's participation in this study is entirely voluntary. At any moment you can discontinue from the study, if you want.

Cost: From this study you will not get any money and you have not to pay any.

Privacy: Your privacy will be maintained during the process of data collection. Confidentiality of all gathered information will be maintained and will be used only for study purpose. Your personal information will not be disclosed to others.

Questions: If you have any question then please ask me. I will try to give answer. If you want to know anything in future then please contact with me by mobile phone (01718779874).

Giving consent: I have understood that, participation of this study is entirely voluntary and at any time I have right to discontinue the study.

I have read above information/above information has been read in front of me and I am agreed to enroll in your study.

Thank you for your co-operation.

…… ……

Signature of the investigator **Signature of the guardian**

List of abbreviations:

BSMMU – Bangabandhu Sheikh Mujib Medical University

NICU – Neonatal intensive care unit

AGA – Appropriate for gestational age

SGA – Small for gestational age

LMP – Last menstrual period

IUGR – Intrauterine Growth Restriction

IRB – Institutional review board

USG – Ultra sonogram

CPAP- Continuous Positive Airway Pressure

bCPAP- Bubble Continuous Positive Airway Pressure

APPENDIX-IV

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APPENDIX-V

Timetable of the study:

	1 month	1 month	13 months	2 months	1 month
Article review and Topic selection					
IRB clearance					
Data collection					
Follow up					
Data analysis Report writing					

APPENDIX-VI

Budget	
Books and literatures	25,000 Taka
Pulse oximetry	20,000 Taka
Usg of brain	500×51=25,500
Chest X ray	1200×51= 61,200
Echocardiogram	2000 × 51=102,000
Septic screen Blood culture sensitivity	580 x 66 = 38,280 Taka 800 x 66 = 52,800 Taka

Data analysis	25,000 Taka
Printing	25,000 Taka
Total	**282,980**

Funding source: Self