**STUDY PROTOCOL**

To compare the early versus late initiation of Trophic feeding in preterm infants on duration of stay in high dependency unit: A non-randomized clinical trial.

**OPERATIONAL DEFINITIONS:**

**Trophic Feeding:**

It is the practice of feeding minute volumes of enteral feeds to preterm infants in order to stimulate development of their immature gastrointestinal tract and to prevent gastrointestinal mucosal atrophy.

**High Dependency Unit:**

High Dependency Unit is established to care for patients who need high level of monitoring and management for their condition e.g. Preterm infants.

**Preterm:**

It is defined by WHO as an infant delivered before 37 weeks of gestation.

**HYPOTHESIS:**

Early initiation of Trophic feeding (<48hrs postnatal age) as compared to Late(>72hrs postnatal age) of preterm infants is associated with less duration of stay in high dependency unit which is an important neonatal outcome with respect to improved survival of preterm infants.

**MATERIALS AND METHODS:**

**Study Design:**

Prospective non-randomized Trial

**Setting:**

Neonatal High Dependency Unit, Pediatric Department, Lady Reading Hospital, Peshawar.

**Duration of Study:**

Minimum 3 months after approval of synopsis.

**Sample Size:**

Sample size is 120 preterm infants in each group using 11+10 SD in early feeding group and 15+12 SD in late feeding group8 with 95% confidence level and 80% power of test under WHO software for sample size determination.

**Inclusion Criteria:**

1. Preterm infants ( 28 weeks to 36 weeks) of gestation.
2. Both male and female preterm infants.
3. Birth weight (>1000g to 2500g)
4. < 3 days postnatal age at the time of admission to hospital.

**Exclusion Criteria:**

1. Major congenital anomaly. (e.g. congenital heart disease, syndromic infants)
2. Preterm infant on inotropic drug support.
3. Preterm infants with severe respiratory distress.

**DATA COLLECTION PROCEDURE:**

The study is conducted after approval from hospital Ethical and Research Committee. All admitted preterm infants meeting the inclusion criteria are included in the study after taking written informed consent from their parents. The purpose and benefits of the study are explained to all the parents. All included preterm infants are allocated into two groups by birth date. In group A trophic feeding of preterm infants will be initiated early (<48hrs postnatal age). In group B it is initiated late (>72hrs postnatal age). Neonatal outcome is assessed by duration of stay in high dependency unit in (number of days).

**DATA ANALYSIS PROCEDURE:**

The data is entered into statistical package for social sciences (SPSS version 23) for analysis. Mean + Standard deviation are calculated from numerical variables like age, duration of hospital stay. Frequency and percentages are calculated for categorical variables like gender. T-test is used to compare duration of stay in high dependency unit of both groups while keeping p-value < 0.05 as significant. All the results are presented as Tables/Charts.