Full study protocol and statistical analysis plan

Official Title of the study:

Umbilical cord and maternal blood concentrations of melatonin, soluble urokinase-type plasminogen activator receptor, and orosomucoid 2 in pregnancy complicated by preterm premature rupture of the membranes and histological chorioamnionitis

Date of the document:

October 2020.

Contents:

1. Participant Flow

Recruitment Details

This observational case-control study will be conducted at the Department of Obstetrics and Gynecology, Cengiz Gokcek Public Hospital, Gaziantep, Turkey, between October 2020 and October 2021. The protocol was approved by the Ethics Committee for Clinical Research of Gaziantep University (reference no: 2020/276). The study strictly will be adhered to the principles of the Declaration of Helsinki. All subjects will be included in the study gave oral and written informed consent. 88 women were enrolled in the study in two groups.

Pre-assignment Details

The authors first will be assessed the recruited people to ensure meeting the inclusion and exclusion criteria. The inclusion criteria will be made according to the official documents.

Arm/Group Information *

There are two groups in the study.

Arm/Group Title *

preterm premature rupture of membranes group

Control group

2. Baseline Characteristics

To detect significant difference between groups according to lead levels with a moderate effect size (Cohen's d =1), minimum required sample size was estimated as 44 for each group (α=0.05, 1-β=0.80). Power analysis was performed by using G power package version 3.1. Kolmogorov Smirnov and Shapiro Wilk tests will be used to test the normal distribution of data. For comparing groups (PPROM/control) the student t-test will be used for variables that have a normal distribution, and the Mann Whitney U test will be used for variables that have not a normal distribution. The ROC analysis will be applied for the determination of cut-off point for variables. Moreover, Spearman correlation test will be used for the relationship of between variables. SPSS for Windows 22.0 and Medcalc programs will be used for statistical analysis. $p<0.05$ will be accepted as statistical significance.

3. Outcome Measures

Primary Outcome Measures: melatonin, soluble urokinase-type plasminogen activator receptor, and orosomucoid 2 concentrations

Secondary Outcome Measures: composite neonatal outcome (infant weight at delivery, neonatal intensive care unit hospitalization, and APGAR scores etc.)

Tertiary Outcome Measures: obstetric ultrasound examination and fetal-maternal assessment

4. ***Endpoints of the study:***

The primary outcome in these analyses will compare maternal serum melatonin, soluble urokinase-type plasminogen activator receptor, and orosomucoid 2 measurements levels in study group and control group.

5.Limitations and strengths:

There will strengths of this study. The women participating in the study will recruit not received any treatment for PPROM at admission.

6. Certain Agreements

The authors declare that they have no conflict of interest.

7. Results Point of Contact

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