Full study protocol and statistical analysis plan

Official Title of the study:

Analysis of maternal plasma/urine/hair magnesium and vanadium levels in preeclampsia

Date of the document:

May 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 May 2020 and February 2021. The protocol was approved by the Ethics Committee for Clinical Research of Gaziantep University (reference no: 2020/130). 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. Two-hundred ten women will be enrolled in the study in two groups.

The investigators included subjects consisted of women with a singleton pregnancy who were diagnosed as having late-onset preeclampsia between 34+0 and 41+0 weeks of gestation. Pregnant women with uncomplicated pregnancies were randomly selected to serve as controls. Other participants with healthy volunteer women as control non-pregnant group.The study population will have consisted of 70 late-onset preeclampsia patients as a study group, 70 participants with normal pregnancies as control pregnant group and 70 participants with healthy volunteer women as control non-pregnant group. All participants included in the study gave oral and written informed consent.

Pre-assignment Details

The authors firstly were assessed the recruited people to ensure meeting the inclusion and exclusion criteria. The inclusion criteria were maken according to the official documents.

Arm/Group Information *

There are three groups in the study.

Arm/Group Title *

Preeclampsia group
Control pregnant group

Control non-pregnant group

2. Baseline Characteristics

To detect significant difference between groups according to variable with a moderate effect size (Cohen's d =0.5), minimum required sample size was estimated as 63 for each group (α=0.05, 1-β=0.80). Power analysis was performed by using G power package version 3.1. 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

The primary outcome in these analyses will be compare magnesium and vanadium levels in LOPE group and the control groups. The secondary outcome will be compare the magnesium and vanadium levels in mild LOPE group and severity LOPE group. Tertiary outcome will be compare the magnesium and vanadium levels in SGA group and non-SGA group.Venous blood sampled from the antecubital veins for measuring plasma concentration of cadmium, lead and vanadium levels. The three metals (cadmium, lead and vanadium) were measured using inductively coupled plasma-mass spectrometry (Thermo Scientific ICAPQc, USA).

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

The primary outcome in these analyses will be compare magnesium and vanadium levels in LOPE group and the control groups. The secondary outcome will be compare the magnesium and vanadium levels in mild LOPE group and severity LOPE group. Tertiary outcome will be compare the magnesium and vanadium levels in SGA group and non-SGA group.

5.Limitations and strengths:

Because our study is observational, we could not eliminate the possibility of unmeasured and/or residual confounding of the reported associations. . These metals will be measured blood, urine and

hair samples. So, these measurements may not reflect the metals exposure levels only recent exposure and will reflect before and during pregnancy.

6. Certain Agreements

This work will be supported by the Scientific Research Project Fund of Yozgat Bozok University.

7. Results Point of Contact

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