

Obstructive sleep apnea (OSA) is a common but underdiagnosed sleep-related breathing disorder affecting over 100 million adults worldwide. OSA is characterized by recurrent episodes of partial or complete obstruction of the upper airways during sleep, leading to hypoventilation and hypoxia. Untreated OSA is associated with significant health complications, including increased risk of hypertension, cardiovascular diseases, diabetes, daytime sleepiness, traffic accidents, strokes, and higher all-cause mortality. It is estimated that up to 90% of OSA cases remain undiagnosed due to a lack of accessible, sensitive, simple, and effective diagnostic methods.

The aim of the project is to identify and evaluate a broad spectrum of blood biomarkers associated with the presence and severity of OSA, as well as monitoring the effectiveness of positive airway pressure (PAP) therapy. The selected blood biomarkers included in the study protocol have previously been identified as potentially reliable screening and diagnostic indicators for OSA patients. Currently, the gold standard for diagnosing OSA is polysomnography, which requires specialized equipment and overnight observation in a sleep laboratory. Clinical practice guidelines and international consensus statements highlight the need for a new clinical tool to assess disease severity. A blood-based biomarker test could significantly simplify and expand the diagnostic process.

The study will involve 120 adult participants aged ≤ 65 years. They will undergo clinical assessments, including medical history, upper airway examinations, and sleep studies. Participants will complete relevant questionnaires. They will then be assigned to either a group without OSA or a group with the condition. At the beginning of the study, blood samples will be collected from all participants. Additionally, OSA patients will be randomly divided into two subgroups: one starting PAP therapy immediately and the other beginning PAP treatment after a three-month delay. Follow-up blood samples will be taken from OSA patients at 3 and 6 months after study enrollment.

Blood biomarkers, including cytokines, chemokines, and oxidative stress markers, will be analyzed across different groups and time points using multiplex ELISA and metabolomic profiling (gas and liquid chromatography, mass spectrometry).

The project will not only evaluate selected biomarkers associated with hypoxia and inflammation but also apply advanced metabolomics to identify known and new OSA biomarkers. This approach will help identify highly sensitive biomarkers that change during treatment. Additionally, blood biomarker levels will be compared between patients with and without OSA, as well as before and after treatment, considering treatment duration, changes in body mass index (normal weight, overweight, obesity), and gender. The study will also analyze biomarker concentrations in relation to OSA severity to better understand the relationship between hypoxia and biomarker profiles.

The expected outcomes of the project may improve OSA diagnostic procedures, enabling earlier detection and better disease monitoring. Improved access to diagnostic methods and effective treatment will enhance patients' quality of life and reduce the risk of OSA-related complications.