PROTOCOL

Title: The Predictive Effect of Soluble Epoxide Hydrolase (SEH) on Depression Treatment, Cognition and Suicide Improvement

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Study Description

Brief Summary:

Depression is the most common mental disease and the second leading cause of chronic disease burden, which is closely related to suicidal behavior. The diagnosis and treatment of depression still lack of effective biological indicators, and about 30% of patients with depression still can not relieve their depressive symptoms after treatment. Previous studies have found that ATP release from astrocytes plays an important role in the occurrence, development and treatment of depression. Epoxy eicosotrienes (eets) are closely related to the function of the nervous system and may be the pathophysiological mechanism of depression. Soluble epoxide hydrolase (SEH) can regulate ATP release by affecting EET degradation, leading to depression like behavior and antidepressant effect, and sEH is closely related to cognitive function of depression.

Detailed Description:

This study is an observational study without any intervention treatment for the subjects. All subjects need to sign the informed consent before screening, and the successful subjects can enter the study. Routine clinical diagnosis and treatment were performed on patients with depression, and the treatment effect of depressive symptoms, neurocognitive function and suicide improvement were evaluated at the 2nd week, 1st, 2nd, 3rd, 6th and 12th months after enrollment, and statistical analysis was conducted. The treatment lasted until the subjects completed the 12th month follow-up or reached any of the withdrawal criteria. This study will clarify the relationship between sEH gene polymorphism and mRNA expression and depression and suicide behavior, and explore the predictive role of soluble epoxide hydrolase sEH in the treatment effect of depression, cognition and suicide improvement during the follow-up study.

Study Design

Study Type :	Observational
Estimated Enrollment :	330 participants
Observational Model:	Cohort
Time Perspective:	Prospective
Target Follow-Up Duration:	12 Months
Official Title:	The Predictive Effect of Soluble Epoxide Hydrolase (SEH) on Depression Treatment, Cognition and Suicide Improvement
Actual Study Start Date :	June 2019
Estimated Primary Completion Date :	June 2023

Groups and Cohorts

Outcome Measures

Primary Outcome Measures :

Change in Hamilton Depression Scale (HAMD-24) [Time Frame: Baseline, the second week, the first month, the second month, the third month, the sixth month and the first year]: Scores ranging from 0-76, with higher scores indicate more severe symptoms

Secondary Outcome Measures :
Change in Columbia-Suicide Severity Rating Scale, C-SSRS [Time Frame: Baseline, the second week, the first month, the second month, the third month, the sixth month and the first year]: Scores ranging from 0-42, with higher scores indicate more severe symptoms

Eligibility Criteria

Study Population
Major depressive disorder:
Patients with major depressive disorder in the outpatient department of psychiatry and psychology of Nanfang Hospital.
Patients diagnosed with severe depressive episode according to the diagnostic and Statistical Manual of mental disorders, 5th Edition (DSM-V);

healthy volunteer:
Healthy volunteer group was recruited by advertisement。
Person who did not meet the DSM-V diagnosis of any mental disease, had no family history of psychiatric disease, and had no history of suicidal behavior.

Criteria
Inclusion Criteria:
1. Voluntarily sign informed consent;
2. Age: 18-65 years old;
3. Elementary school or above, able to understand and complete all inspections and assessments;
4. Did not take any psychotropic drugs (including benzodiazepines) within 2 weeks before enrollment;
5. After routine medical diagnosis by clinicians, they were divided into depression and healthy people.

Exclusion Criteria:
1. Severe somatic or neurological diseases;
2. Mental retardation and dementia;
3. During pregnancy or breastfeeding;
4. Heavy smoking, alcoholism and other substance abuse or dependence (within 3 months before enrollment);
5. Electric shock treatment (within 3 months before enrollment);
6. According to the judgment of the investigator, it is not suitable to participate in this study.