

ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt

Release Date: December 27, 2021

ClinicalTrials.gov ID: NCT05172362

Study Identification

Unique Protocol ID: 01/2011-2520

Brief Title: Short-Term and Long-Term Cognitive Outcomes in Adults After Cardiac Surgery

Official Title: Short-Term and Long-Term Cognitive Outcomes in Adults After Cardiac Surgery: Domain#Specific Cognitive Changes, EEG and Neurovascular Unit Markers

Secondary IDs:

Study Status

Record Verification: December 2021

Overall Status: Recruiting

Study Start: February 2, 2011 [Actual]

Primary Completion: December 31, 2021 [Anticipated]

Study Completion: December 31, 2023 [Anticipated]

Sponsor/Collaborators

Sponsor: Research Institute for Complex Problems of Cardiovascular Diseases, Russia

Responsible Party: Principal Investigator

Investigator: Olga Trubnikova [otrubnikova]

Official Title: Head of Neurovascular Pathology Lab

Affiliation: Research Institute for Complex Problems of Cardiovascular Diseases, Russia

Collaborators: Novosibirsk State University

Oversight

U.S. FDA-regulated Drug: No

U.S. FDA-regulated Device: No

U.S. FDA IND/IDE: No

Human Subjects Review: Board Status: Not required

Data Monitoring: No

FDA Regulated Intervention: No

Study Description

Brief Summary: Adults with coronary artery disease (250 patients) undergoing cardiac surgery participated in the study. The aim is to investigate short-term and long-term cognitive outcomes and the patterns of organization of functional brain systems in ischemic brain damage using high-resolution electroencephalography, domain-specific assessment of cognitive status and analysis of markers of a neurovascular unit (neuron-specific enolase, brain neurotrophic factor).

Detailed Description: Coronary artery bypass grafting (CABG) is one of the most effective ways to surgically correct coronary atherosclerosis. However, the postoperative cognitive decline often develops in patients who undergo CABG. According to various studies, the frequency of postoperative cognitive dysfunction (POCD) after cardiac surgery is 50-80% at the time of hospital discharge and remains present in 20-50% of patients in long-term period after surgery. The presence of POCD is associated with a decrease in surgery effectiveness and impairments in daily functioning, and is a reliable marker of unfavourable long-term prognosis (e.g., dementia and death). This prospective randomized study will be included the adult patients with stable coronary artery disease aged 45–75 years who admitted for planned CABG at the Federal State Budgetary Scientific Institution of Research Institute of Complex Issues of Cardiovascular Diseases. The study complies with the Good Clinical Practice standards and the principles of the Declaration of Helsinki. The study protocol was approved by the institutional Ethics Committee (01/2011-2520). Prior to inclusion in the study, all participants will be provided written informed consent and underwent basic cognitive screening using the Mini-Mental State Examination (MMSE) scale. The exclusion criteria are as follows: life-threatening rhythm disturbances, chronic heart failure (NYHA functional class III and higher), chronic obstructive pulmonary disease, malignant pathology, drug addiction, stroke, and other brain injuries. All the patients will be underwent general medical, neurological, instrumental examinations and extended neuropsychological assessment using the software Status PF as well as electroencephalographical examination 3-5 days before CABG, at 7–10 days after surgery and 5-7 years after CABG. POCD is determined by a 20% decrease in the cognitive indicator compared to that at baseline on 20% of the tests included in the Status PF battery. The serum concentrations of markers of the neurovascular unit (S100b, NSE, and BDNF) will be measured 3-5 days before CABG, within the first 24 h after surgery, and at 7–10 days after CABG.

In summary, the long-term neurophysiological effects following cardiac surgery are poorly understood. Moreover, little is known about the structure of cognitive impairment during the long-term postoperative period and the corresponding functional activity of the brain. The detection of minimal or subclinical signs of brain dysfunction following CABG is still under debate. Prior studies have shown the relationship between EEG abnormalities and cognitive impairment. However, little is known about EEG changes and concentrations of markers of the neurovascular unit in patients after on-pump CABG. To facilitate and improve the diagnostic accuracy, detailed neuropsychological examination using the multichannel digital EEG, serum concentrations of markers of the neurovascular unit and psychometric tests may be used to detect the long-term brain changes associated with postoperative cognitive impairment. Therefore, the study aims to evaluate the neurophysiological outcomes of patients 5-7 years after CABG.

Conditions

Conditions: Postoperative Cognitive Dysfunction
Coronary Artery Disease

Keywords: coronary artery bypass grafting
brain activity
markers of neurovascular unit
cognitive test

Study Design

Study Type: Observational
Observational Study Model: Cohort
Time Perspective: Prospective
Biospecimen Retention: None Retained
Biospecimen Description:
Enrollment: 250 [Anticipated]
Number of Groups/Cohorts: 1

Groups and Interventions

Outcome Measures

Primary Outcome Measure:

1. Postoperative cognitive dysfunction

Postoperative cognitive dysfunction (POCD) is a decline in cognitive functions following surgery and anesthesia, characterized by impairment of attention, concentration, and memory that may have long-term implications.

The cognitive status assessment includes extended neuropsychological testing (the assessment of psychomotor and executive function, attention, and short-term memory from the neuropsychological test battery of the psychophysiological complex software "Status PF" (Rospatent № 2001610233).

[Time Frame: up to 5-7 years after surgery]

Secondary Outcome Measure:

2. Basic cognitive status as measured by the Mini-Mental State Examination (MMSE) scale

The Mini-Mental State Examination (MMSE) is a 30-point questionnaire that is used to measure cognitive status. The possible score in the MMSE test ranged between 0 (minimum) and 30 (maximum). The MMSE tests in this study were given in validated Russian-language versions.

[Time Frame: up to 5-7 years after surgery]

3. Basic cognitive status as measured by the Frontal Assessment Battery (FAB)

Frontal Assessment Battery (FAB) is a test for estimation of frontal type cognitive disorders. The possible score in the FAB test ranged between 0 (minimum) and 18 (maximum). The FAB tests in this study were given in validated Russian-language versions.

[Time Frame: up to 5-7 years after surgery]

4. Basic cognitive status as measured by the Montreal Cognitive Assessment (MoCA)

Montreal Cognitive Assessment (MoCA) is a 30-point test used for screening assessment of cognitive impairment. MoCA scores range between 0 and 30, a score of 26 or over is considered to be normal. The MoCA tests in this study were given in validated Russian-language versions.

[Time Frame: up to 5-7 years after surgery]

Eligibility

Study Population: The adult patients with coronary artery disease aged 45-75 years who were admitted for planned CABG at the Federal State Budgetary Scientific Institution of Research Institute of Complex Issues of Cardiovascular Diseases.

Sampling Method: Probability Sample

Minimum Age: 45 Years

Maximum Age: 75 Years

Sex: All

Gender Based: No

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

1. Planned coronary surgery
2. Written informed consent

Exclusion Criteria:

1. Depression (BDI-II score more than 8)
2. Dementia (MMSE score less than 24; FAB score less than 11; MoCA score less than 20)
3. Life-threatening rhythm disturbances
4. Chronic heart failure (NYHA functional class III and higher)
5. Chronic obstructive pulmonary disease
6. Malignant pathology
7. Drug addiction
8. Stroke
9. Brain injuries

Contacts/Locations

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Locations: **Russia**

Federal State Budgetary Scientific Institution of Research Institute of Complex Issues of Cardiovascular Diseases

[Recruiting]

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IPDSharing

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References

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Available IPD/Information:

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