

INDIVIDUAL REGISTRATION CARD (IRC)

Appendix No. 5

STUDY "DEVELOPMENT OF A PROGRAM FOR EARLY DIAGNOSTICS AND TREATMENT OF
CARDIOTOXIC COMPLICATIONS CAUSED BY CHEMOTHERAPY OF BREAST CANCER"

RESEARCHER _____ Recruitment date _____

Patient's code _____ Indiv. identification number _____

Phone _____

Address _____

Inclusion Criteria:

Age 18 years and older;

Outpatient or inpatient treatment at the University's Medical Center with a verified diagnosis of breast cancer of any stage;

Administration of targeted therapy in case of confirmed Her2 positive status and/or drugs from the Anthracycline group.

Exclusion Criteria:

A history of the cardiotoxic effect of chemotherapy, regardless of the statute of limitations;

Progression of coronary artery disease or decompensation of CHF in the previous 6 months;

Simpson left ventricular ejection fraction $\leq 40\%$;

Decompensation of comorbid pathology (endocrine disorders, diseases of the liver, kidneys, bronchopulmonary system) in the previous 3 months.

GENERAL INFORMATION:

Name _____

Date of Birth: _____ Age _____ Gender _____

Ethnicity: Asian - 1; European - 2; I refuse to answer - 3.

Marital status: Single/Not married – 1; Married – 2; Divorced -3; Widow/widower – 4;

I refuse to answer – 5.

Occupation (main occupation for the last 12 months):

State employee -1; Private sector employee -2; Entrepreneur - 3; Student - 4; Housewife - 5; Retired - 6;

Unemployed (able to work) - 7; Disabled - 8; Refuse to answer - 9.

Height _____ (cm); Weight _____ (kg); BMI _____ (kg/m^2)

I.BREAST CANCER FEATURES

Hereditary factor: Yes - 1; No - 2; **Menopause:** Yes - 1; No - 2; **BC localization:** Right - 1; Left – 2;

Clinical staging: 1 – I St; 2 – IIA St; 3 – IIB St; 4 – IIIA St; 5 – IIIB St; 6 - IV St.

Tumor histotype:

- 1 - invasive carcinoma without specification;
- 2 - intraductal cancer;
- 3 - infiltrating ductal cancer;
- 4 - lobular cancer;
- 5 - carcinosarcoma.

Clinical classification of the tumor:

- 1 - nodal cancer
- 2 - diffuse form - mastitis-like cancer
- 3 - diffuse form - edematous-infiltrative cancer
- 4 - diffuse form - Paget's cancer
- 5 - diffuse form - shell cancer
- 6 - diffuse form - erysipelalous cancer
- 7 - diffuse form - others, without specification.

Immunohistochemical data:

- 1 – Triple negative TNBC (ER (-), PR (-), Her-2-neu – neg, Ki 67 – any);
- 2 – Luminal type A (ER (+) and/or PR (+), Her-2-neu – neg., Ki 67 – < 20%);
- 3 – Luminal B type (positive) (ER (+) and/or PR (+), Her-2-neu – pos., Ki 67 – any);
- 4 – Luminal B type (negative) тип (ER (+) and/or PR (+), Her-2-neu – neg., Ki 67 – > 20%);
- 5 – Her-2-positive type (ER (-), PR (-), Her-2-neu – pos., Ki 67 – any).

II.VISITS

Factors	Visit 0	Visit 1	Visit 2	Visit 3	Visit 4
Smoking, yes-1, no-2					
Physical activity (hour, min)					
SBP					
DBP					
Heart rate, beats/min					
Hemoglobin, g/l					
Leukocytes, 10 ⁹					
Platelets, 10 ⁹					
Blood glucose, mmol/l					
Creatinine, mmol/l					
Bilirubin, mmol/l					
Total cholesterol, mol/l					
Arterial hypertension, yes-1, no - 2					
Diabetes mellitus, yes-1, no - 2					
IHD (functional class I,II,III,IV)					
CHF (functional class I,II,III,IV)					
History of stroke					
CHARLSON, scores					
6-minute walk test, meters					
6-minute walk test, functional class I,II,III,IV					
Cardiac protectors					
1ACE inhibitor/ARA blockers					
2Beta-blockers					

3Calcium channel blockers					
4Statins					
5Trimetazidine and analogues					
6 Other (write in)					
7Other (write in)					
BC treatment					
Doxorubicin, dose/regimen					
Trastuzumab, dose/regimen					
Radiation therapy, dose/regimen					
Surgical treatment: Radical -1; Sectoral-2					
Biomarkers					
cTn, ng/mL					
BNP, pg/mL					
CRP, mg/L					
D dimer, mg/L					
MPO, U/ml					
Gal-3, ng/ml					
ECG, HM, EchoCG					
ECG, code					
Holter monitoring*, code					
LVEF (Simpson), %					
GLS, %					
Cardiotoxicity type, code					
* - 0,2,4 visits					

CHARLSON Comorbidity index

DISEASES	SCORES
Myocardial infarction	1
Chronic heart failure	1
Peripheral artery disease	1
Cerebrovascular disease	1
Dementia	1
Chronic lung disease	1
Connective tissue disease	1
Peptic ulcer	1
Mild liver damage	1
Diabetes	1
Hemiplegia	2
Moderate or severe kidney disease	2
Diabetes mellitus with organ damage	2
Malignant tumor without metastases	2
Leukemia	2
Lymphomas	2
Moderate or severe liver damage	3
Metastatic malignant tumors	6
AIDS (disease, not viremia)	6

Age	40-49 years old - 1 score; 50-59 years old - 2 scores; 60-69 years old - 3 scores; 70-79 years old - 4 scores, etc.
CHARLSON comorbidity index, scores	

6-minute walk test

Parameter	initially	After test
Shortness of breath (Borg scale)		
Weakness (Borg scale)		
Heart rate		
Arterial BP		

Pauses or stops during the test: yes / no; time _____ amount _____

Symptoms during the test: angina pectoris _____ dizziness _____

leg pain _____ weakness _____ other _____

Number of laps _____ Distance covered _____

FC score NYHA

The severity of CHF (NYHA)	Distance 6-minute walk
I FC	426-550
II FC	301-425
III FC	151-300
IV FC	<150

Complications of Chemotherapy

Factors (code)	Visit 0	Visit 1	Visit 2	Visit 3	Visit 4
1 Cardiotoxic (code)					
2 Hematopoietic system					
3 Thromboembolic complications					
4 Pericarditis					
5 Gastrointestinal tract					
6 Respiratory system					
7 Urinary system					
8 Allergic reactions					
9 Neurotoxicity					
10 Toxic effect on the skin and appendages					
11 Toxic hyperthermic reactions					
12 Toxic phlebitis					

Chemotherapy outcomes

Factors (code)	Visit 0	Visit 1	Visit 2	Visit 3	Visit 4
1 According to the plan, without complications					
2 ChT correction due to CT					

complications					
3 ChT suspension due to CT complications					
4 Correction of CT due to non-CT complications					
5 ChT suspension due to non-CT complications					
6 Completion of chemotherapy, %					
7 Death (date, cause)					
8 Dropped out of the study					

Codes for ECG and Holter monitoring

ECG codes

- 1 - Norm;
- 2 - Sinus tachycardia (HR> 90 beats / min);
- 3 - Sinus bradycardia (HR<60 bpm);
- 4 - Atrial extrasystoles;
- 5 - Ventricular extrasystoles;
- 6 - Atrial fibrillation
- 7 - AVB I st, AVB II st Mobitz 1;
- 8 - AVB II st Mobitz 2, AVB III st;
- 9 - Bundle branch block;
- 10- ST segment depression/elevation;
- 11- Prolongation of QT corrected.

HMECG codes

- 1-Norm;
- 2-Atrial extrasystoles single, paired;
- 3-Atrial extrasystoles group, paroxysms of atrial tachycardia;
- 4-Ventricular extrasystoles Laun I, II, III;
- 5- Ventricular extrasystoles Laun IV, V;
- 6-Atrial fibrillation;
- 7-AVB Ist, AVB II st Mobitz 1;
- 8-AVB II st Mobitz 2, AVB IIIst;
- 9- Bundle branch block;
- 10-ST segment depression/elevation;
- 11- Corrected QT prolongation.

Complications of Chemotherapy (codes)

Cardiotoxic (codes):

- 1-Subclinical LV dysfunction;
- 2-Clinical LV dysfunction;
- 3-Rhythm and conduction disorders;
- 4-Arterial hypertension
- 5-Angina pectoris;
- 6-Pulmonary hypertension;
- 7-Pericarditis;
- 8-Thrombosis and thromboembolism;
- 9-Peripheral vascular disease and stroke

Type of cardiotoxicity:

- A-Acute;
- B-Subacute;
- C-Chronic

Hematopoietic system:

- 1 - Anemia
- 2 - Thrombocytopenia
- 3 - Leukopenia

Note_____

Gastrointestinal tract

- 1- Nausea and vomiting
- 2 - Stomatitis/mucositis
- 3 - Toxic enterocolitis
- 4 - Toxic hepatitis

Respiratory system

- 1-Acute respiratory failure
- 2-Bronchospasm
- 3-Pneumonitis, bronchitis
- 4-Pulmonary edema

Note_____

Urinary system

- 1-Nephrotoxicity
- 2-Toxic cystitis

Note_____

Allergic reactions

- 1-Anaphylactic shock
- 2-Urticaria

3-Bronchospasm

Note_____

Neurotoxicity

1-Peripheral

2-Central

3- Psychovegetative disorders

Note_____

CARDIOVASCULAR RISK STRATIFICATION FOR UPCOMING CHEMOTHERAPY TREATMENT

Appendix No. 6

Study "DEVELOPMENT OF A PROGRAM FOR EARLY DIAGNOSIS AND TREATMENT OF
CARDIOTOXIC COMPLICATIONS CAUSED BY BREAST CANCER CHEMOTHERAPY"
(PREDICATE)

PATIENTS' CODE _____ DATE OF FILLING IN _____

RISK FACTOR	HAZARD LEVEL OF THE RISK FACTOR	PATIENT'S RISK LEVEL
Existing chronic heart failure or dilated cardiomyopathy	Very high	
Previous severe valvular heart disease	High	
Past myocardial infarction and/or revascularization	High	
Stable angina	High	
Baseline left ventricular ejection fraction <50%	High	
Initial left ventricular ejection fraction 50-54%	Intermediate	
Elevated Troponin at baseline	Intermediate	
Initially elevated NT-proBNP or BNP	Intermediate	
Age over 80	High	
Age 65-79 years	Intermediate	
Arterial hypertension	Intermediate	
Diabetes mellitus	Intermediate	
Chronic kidney disease	Intermediate	
Prior treatment with Anthracyclines	High	
Prior Radiation Therapy	High	
Prior anticancer therapy without Anthracyclines	Intermediate	
Long history of smoking	Intermediate	
Obesity with body mass index >30 kg/m ²	Intermediate	
TOTAL RISK OF CARDIOTOXIC COMPLICATIONS		
<p>*Note: Low risk of cardiotoxicity (CT) - 1 intermediate risk factor (RF) or no RF; Intermediate risk of CT - from 2 to 4 intermediate risk factors; High risk CT - more than 5 intermediate risk factors or 1 high risk factor; Very high risk CT - presence of very high risk factor.</p>		