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Research protocol
4th National Registry of Cardiovascular Surgery (CCV) in Argentina

-Version N ° 3- 8 of JULY 2021

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PROTOCOL SUMMARY

➢ **Title**

1- Prospective registry of patients undergoing CCV in Argentina

➢ **Study Phase**

1- Prospective Registry (IV)

➢ **Evaluation**

1- Follow-up of patients during hospitalization and 30 days after surgery.

➢ **Primary Objectives**

1.a.

Determine the evolution and surgical complications in patients undergoing CCV

1 B.

To determine the association between different risk variables during the intranosocomial stay and at 30 days of discharge including nosocomial readmission during the 30-day follow-up.

➢ **Secondary Objectives**

To determine the association between different variables that occurred before, during and after the surgical intervention.

To determine the association between different variables of risk at discharge and the rate of complications, including
mortality and readmissions during the 30 days following discharge, such as:
Cardiovascular mortality, all-cause mortality, rehospitalization, infectious complications.

To determine the association between different variables with cardiovascular mortality in relation to CCV.

Assess eventual complications 30 days after hospital discharge

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➢ **Study Design**

National, multicenter, analytical, prospective cohort study for prognostic evaluation in patients undergoing
cardiovascular surgery (CCV)

➢ **Sample Size**

The largest number of patients (between 2000 and 3000) will be enrolled during a set period of time (1 year), from
October 1, 2020 to September 30, 2021

➢ **Eligibility Criteria**

- Over 18 years
-

Myocardial revascularization surgery

Valvular surgeries

Ascending Aortic Surgery

Type A Aortic Dissection Surgery

Combined surgery

➢ **Exclusion Criteria**

Cardiovascular surgery for congenital pathologies

Peripheral vascular surgery

Cardiovascular surgery secondary to trauma

Thoracic and abdominal aorta pathology

Other surgeries

➢ **Procedures**

Various centers are included nationwide with a CCV service capable of admitting and intervening patients with
criteria already established.
They are arranged below:
Leben Health
Private Hospital Santa Clara de Asis
Dr Alberto Duhau Hospital
Pasteur Clinic
Sanatorio Juan XXIII
Private hospital
San Martin Sanatorium
Cordoba Hospital
Spanish Hospital
Spanish Hospital / Pami 2 Polyclinic / Italian Hospital / IPAM
Santa Clara Clinic
CARDIOMED
Cosme Argerich Hospital
Spanish Society of Mutual Aids
CCV- St. Clara San Juan

Tucuman Institute of Heart Diseases
Italian Hospital of Mendoza
FIG Dr. Oscar Alende
HOSPITAL FOUNDATION / CENTRAL MILITARY HOSPITAL
Spanish Hospital
Galen Sanatorium
San Juan de Dios Hospital
Guemes sanatorium
Dr. Cesar Milstein Hospital
CEMIC
HIEAYC SAN JUAN DE DIOS
Sanatorio de la Cañada
Hospital de Clinicas Jose de San Martin
South Mendocino Spanish Hospital
Sanatorium of La Trinidad Miter

La Sagrada Familia Clinic
ICBA
Santorio de la Trinidad Quilmes
British Sanatorium of Rosario
Bazterrica
Santa Isabel Clinic
Htal Churruca
Sanatorio Del Salvador
Sanatorio Anchorena San Martin
Carrillo Hospital
Sanatorium San Juan Bautista
Sanatorio Juan XXIII
Sanatorio Juan XXIII
Argerich Hospital
Argerich hospital
HIGA President Peron
Spanish Hospital Buenos Aires
Belgrano Adventist Clinic
German Hospital
Syrian Lebanese Hospital
BRITISH Hospital
Favaloro Foundation
Private Clinic velez sarsfield
Yunes Clinic
Hospital Italiano De Bs.As.
Juan Domingo Peron High Complexity Hospital
Allende Sanatorium
Sanatorio de la Cañada
Cardiology institute
British sanatorium
Htal Eduardo Wilde
Presidente Peron Hospital
Hospital El Cruce
Private hospital
Pasteur Clinic
Hospital Escuela de Agudos Ramon Madariaga
Bernal Sanatorium
San Roque Sanatorium
Spanish society and clinic santa clara mendoza

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Cesar Milstein Hospital
San Luis Cardiovascular Institute
Galen Sanatorium
ICBA
Instituto de Cardiologia de Rosario "Dr. Luis Gonzalez Sabathie"
Malvinas Argentinas Sanitary Pole
Delta Sanatorium
Sanatorio Dr Julio Mendez
Model Institute of Cardiology
Sanatorio San Jorge SRL
policlinico san lucas / clinica regional del sud
Private Hospital of the Mar del Plata Community
SANTA FE SANATORIO MEDICO SURGICO
Zabala SMG Clinic
Decentralized Public Hospital Dr Guillermo Rawson
Patients are evaluated during hospitalization eligibility criteria and the Informed Consent will be signed. (CI) according to current regulations.

The respective filling of the files designed with the necessary Pre-surgical data will be carried out, during the
surgical procedure and postoperative.
Telephone calls will be made from the Argentine Society of Cardiology (SAC) and / or College of Cardiovascular Surgeons (CCV), with a questionnaire 30 days after discharge.
The principal investigators of the study are:
Dr Esteban Romeo
Dr Adrián Lescano
It will be assigned during the inclusion of investigator patients for each of the centers, who will be responsible for completing the form (*CRF*) and sending the registered data.

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Additional Information

Introduction

More than ten years have passed since the last CCV registration in the Argentine Republic
In recent decades, the evolution of CCV has shown a reduction in the rate of complications and mortality in centers
specialized

objectives

Record
1. determine complications, mortality and hospital stay, as well as evolution at 30 days after CVD
In our country
2. Compare our variables with those exposed by the different international scores and thus be able to predict the
estimated evolution of our patients.

Substudy
1. Determine the association between different variables, complication rate and mortality 30 days after discharge.

Proposed design

The study consists of **2 stages** , with the voluntary participation of the different centers, which is divided into nosocomial phase and phase a
30 days after discharge
Prospective multicenter registry of prognostic correlation with various risk scores in patients undergoing CCV and
evolution of the same 30 days after discharge

Material and methods

Patients who meet the eligibility criteria described above are included from October 1, 2020
The protocol consists of 2 stages:
1) Nosocomial Phase: a descriptive record is made of the referred variables and the risk parameters upon discharge from
the patients
2) 30 days after discharge, the respective forms will be filled out for the final evaluation of
patients who have undergone CCV and discharged from participating institutions

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Specific Protocol (Operational Definition of Variables):

A complete clinical history of the patient is taken (according to usual practice) and the data is filled out in the Pre, Intra and Post-surgical stage according to what is established in the form

Affiliate Information and Background

Record ID

_____

Date of admission

_____

Acronyms for Name and Surname

_____

Last 3 digits of document number

_____

(Last 3 digits only)

Age _____ gender_____ Weight (kg) _____ Height (cm) _____

Public Hospital Coverage

PAMI

Social work

Prepaid

Particular

Telephone

_____

Phone 2

_____

Email

_____

Background

Arterial hypertension Yes No

Diabetes Yes No

Diabetic retinopathy Yes No

Dyslipidemia Yes No

Ex-smoker tobacco

I never smoke

Smokes daily

Smokes occasionally

It is unknown

Hyperuricemia Yes No

HIV Yes No

Systolic LV dysfunction Yes No

Heart failure Yes No

Myocardial infarction No <30 days> 30 days

Myocardial revascularization surgery Yes No

Valve surgery Yes No

Other cardiovascular surgery Yes No

Type of cardiovascular surgery

_____

(Describe ...)

Coronary angioplasty Yes No

Immunocompromise Yes No

Mediastinal radiation Yes No

Stable chronic angina Yes No

Chronic atrial fibrillation Yes

No

Unstable angina Yes No

Family history of coronary disease Yes No

Peripheral vascular disease Yes No

Pulmonary Hypertension Yes No

Cerebrovascular disease Yes No

Syncope Yes No

SAHOS Yes No

COPD No

Mild

Moderate

Severe

It is unknown

Remote Non-Recent Pneumonia
It is unknown
Did you have COVID-19 within the month prior to surgery? If not
Liver disease Yes No
Illicit drug use No Recent Remote
It is unknown
Alcohol abuse No
<1 glass per day
2 to 7 glasses per day
> 7 glasses per day
It is unknown
Usual medication Aspirin

10
Clopidogrel
Ticagrelor
Prasugrel
Statins
Beta-blockers
ACEI
ARA-II
Loop diuretics
Thiazides
Spirinolactone
Insulin
Oral hypoglycemic
Anticoagulants
Suspension P2Y12 Inhibitors Yes No
Days of suspension of Inhibitors P2Y12
_____
Frail patient Yes No
I use a fragility score Yes No
Fragility score
_____
Other background
_____

Presurgical data

Presurgical diagnosis Heart failure
Endocarditis
Acute aortic syndrome
Ischemic heart disease
Valvular disease
Pericardial involvement
Other
Related signs and symptoms Dyspnoea
Precordial pain
Edema in lower limbs
Febrile syndrome
Syncope
Palpitations
Neurological focus
Acute Pulmonary Edema
Tachyarrhythmias
Bradyarrhythmias
Other

eleven
(Select at least one)
Coronary heart disease Yes
No
Left Coronary Trunk Injury Yes

No
Number of glasses
_____
Vessels affected Descending Anterior
Diagonal
Circumflex
Lateroventricular
Right Coronary
Other
Valvular disease Yes
No
Type of valve pathology Aortic stenosis
Aortic insufficiency
Mitral stenosis
Mitral Insufficiency
Pulmonary stenosis
Pulmonary insufficiency
Tricuspid stenosis
Tricuspid Insufficiency
(Select at least one)
Combined Surgery Yes
No
(Valular + Bridges)
Type of procedure Scheduled
Urgency
Emergency
Laboratory upon admission
Hematocrit _____ Leukocytes _____ Platelets _____
Blood glucose _____ Uremia _____ Creatinine _____
Cholesterol _____ HDL _____ LDL _____
Triglycerides _____ Total bile _____ GOT _____
GPT _____
Electrocardiogram
Rhythm _____ Frequency _____
Prolonged PR _____ AV block _____
Right bundle branch block _____ Left bundle branch block _____
ST elevation _____ ST elevation _____

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T wave inversion _____
SCORES
We ask you to complete the following values by calculating them. Click on the following links to enter the respective online calculators:
EUROSCORE: https://www.rccc.eu/Cardio/euroscoreII.html
ARGENSCORE: http://argenscore.org/calculadora.aspx
EUROSCORE II mortality (%) _____
ARGENSCORE score _____
ARGENSCORE Mortality _____
Use of pre-surgical IACB Yes No
Use of Swan Ganz presurgical Yes No
Use of presurgical inotropics Yes No

Intraoperative

Date of surgery
_____
Patient condition Stable Unstable
Use of ventricular assist Yes No
Use of BCIAo Yes No
Required transfusion of blood products Yes No
Red blood cells
_____
(Units)
Platelets
_____
(Units)

Plasma
_____
(Units)
Extracorporeal circulation Yes No
CEC time
_____
(Minutes)
Clamping time
_____
(Minutes)
CRM was carried out Yes No
Left breast bridge Yes No
Right breast bridge Yes No
Radial bridge Yes No
Number of radial bridges
_____

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Venous bridge Yes No
Number of venous bridges
_____
Endarterectomy Yes No
Quality of the distal beds Good Regular
Bad
Valve surgery was performed Yes No
Aortic valve plastic Yes No
Aortica Jacoub plastic technique
David
Aortic valve replacement Yes No
Type of Biological Aortic Valve with stent
Biological without stent
Single Disc Mechanics
Clamshell Mechanics
Biological valve type Aortic Pericardial
Swine
Bovine
Aortic biological valve measurement
_____
(Number)
Brand of Aortic Biological Valve
_____
Aortic mechanical valve measurement
_____
(Number)
Aortica mechanical valve brand
_____
Ring enlargement Yes No
Ring enlargement technique
_____
Plastic Mitral Valve Yes No
Plastic was made on the previous valve
Posterior leaflet
Mitral valve replacement Yes No
Biological Mitral Valve Type with Stent
Biological without stent
Single Disc Mechanics
Clamshell Mechanics
Type of Mitral Pericardial Biological Valve
Swine

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Bovine

Mitral biological valve measurement
_____
(Number)
Mitral Biological Valve Brand
_____
Mitral mechanical valve measurement
_____
(Number)
Mitral mechanical valve brand
_____
Intra-operative TEE in mitral surgery Yes No
Plastic Tricuspid Valve Yes No
Tricuspid valve replacement Yes No
Biological Tricuspid Valve Type
Mechanics
Tricuspid biological valve measurement
_____
(Number)
Brand of Tricuspide Biological Valve
_____
Tricuspid mechanical valve measurement
_____
(Number)
Tricuspid mechanical valve brand
_____
Pulmonary valve plastic Yes No
Pulmonary valve replacement Yes No
Biological Pulmonary Valve Type
Mechanics
Pulmonary biological valve measurement
_____
(Number)
Pulmonary biological valve brand
_____
Pulmonary mechanical valve measurement
_____
(Number)
Pulmonary mechanical valve brand
_____
Ross Surgery Yes No

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Ascending Aortic Surgery Yes No
Type of Ascending Aorta Surgery Bentall de Bono
Resuspension
WHEAT (supracoronary)
Tirone David
Yacoub
Cabrol
Tubular portion replacement
Reattachment of supra-aortic vessels
Other
Aortic prosthesis placement Yes No
Aortic prosthesis measurement
_____
(Number)
Intra-surgical hemorrhage Yes No
Cause of Medical Surgical Bleeding
Intra-surgical arrest Yes No
Readmission to CEC Yes No
Other complications
_____

Postoperative

Via air Fast track (extubate)

Intubated
Extubates at <6 hours
6 to 12 hours
12 to 24 hours
> 24 hours
Long ARM Yes No
ARM days
_____
Reintubation Yes No
Hemorrhage Yes No
(> 500 ml in the 1st hour or> 400 ml in the 2nd hour or
> 300 ml in the 3rd hour or> 200 ml in the 4th hour or
> 100 ml in the 5th hour)
Type of Hemorrhage Medical Surgical
Surgical examination required Yes No
Surgical resolution Yes No
Transfusion of blood products Yes No
Right Ventricular Dysfunction Yes No
(Persistent arterial hypotension, blood pressures

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Elevated ventricular (right atrium) filling,
low cost with need for intervention
pharmacological and eventually mechanical (TAPSE <17
mm or visual impression by Echocardiography of
RV dysfunction))
Low expenditure syndrome Yes No
(Systolic blood pressure <90 mmHg, pale and
skin coldness, lack of capillary filling,
clouding and oliguria, heart index
<2.2
L / min / m2, pulmonary capillary pressure> 18 mmHg, with
inotropic and / or balloon requirement
intra-aortic counterpulsation (IACAB))
Inotropic / vasopressor requirement Yes No
Inotropics / Vasopressors used Dopamine
Dobutamine
Milrinone
Levosinmendan
Noradrenaline
Vasopressin
Adrenalin
Swan Ganz requirement Yes No
Perioperative myocardial infarction Yes No
Definition of perioperative infarction according to the center Development of Q waves
per ... Increased CPK MB â ‰ ¥ 80 IU / ml
Parietal alterations on echocardiogram
Troponin T or I> 10 times its baseline value
US troponin> 10 times baseline
Atrial fibrillation Yes No
Atrioventricular block Yes No
Complex ventricular arrhythmia Yes No
Transient pacemaker Yes No
Permanent pacemaker Yes No
I do prophylaxis for postoperative AF Yes No
Drug used
_____
POP day of initiation of prophylaxis for AF
_____
Renal failure Yes No
(Increase in creatinine above 50%
with respect to the baseline value and / or

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hemodialysis)
Hemodialysis Yes No
Stroke Yes No
(Focal and / or diffuse brain injury confirmed by
clinical findings and / or computed tomography with
sensory or motor sequelae upon discharge of the patient)
Transient ischemic accident Yes No
Psychiatric disorders Yes No
(Any of the following: delirium, hallucinations,
psychomotor arousal)
Required treatment with ... Risperidone
Quetiapine
Haloperidol
Other
Respiratory distress syndrome Yes No
(Infiltrate in 4 quadrants - PCP <18 - PAFI <200)
Fever without obvious focus Yes No
Sepsis Yes No
(Suspected or documented infection with dysfunction of
target organ and at least two of the following
criteria: Temperature> 38 Â ° C or <36 Â ° C,
White blood cell count greater than 12,000 uL or less
at 4000 uL, Tachycardia, Tachypnea> 30 rpm,
Altered mental state, Positive culture of
primary focus of infection, mean arterial pressure
less than 70 mm Hg for a minimum
fingers
hours, poor distal perfusionâ € ¨)
Urinary infection Yes No
Respiratory infection Yes No
Surgical wound infection Yes No
Superficial wound infection Yes No
Saphenous wound infection Yes No
Sternal infection Yes No
Mediastinitis Yes No
Sternal reopening requirement Yes No
Sternal reopening POP day
_____
Sternal mechanical instability Yes No
COVID-19 infection development during
internment

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If not
TOTAL days of hospitalization until discharge
_____
POSTOPERATIVE days until discharge
_____
Discharge
Alive
Dead _____
Death cause:
Infectious
Cardiovascular
Distributive shock
Hemorrhage
Cardiac tamponade
Stroke
Respiratory distress
Multi-organ failure
Another cause
Death from infectious cause: Mediastinitis Pneumopathy Sepsis Other

Identified germ
_____
Death from cardiovascular cause: Myocardial infarction Arrhythmia Heart failure
Pre Registration Laboratory
Hematocrit _____ Blood glucose _____
Uremia _____ Creatinine _____
Medication at discharge ASA
Clopidogrel
Ticagrelor
Prasugrel
Statins
Beta-blockers
Sartan
ACE inhibitors
Loop diuretic
Thiazide
Spironolactone
Insulin
Oral hypoglycemic
Anticoagulants
Investigator Notes
_____

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Follow-up

Re-internment Yes No
(Within the first 30 days after discharge)
Cause of re-admission:
Heart failure
Respiratory insufficiency
Renal insufficiency
Sepsis:
Other
Sepsis Yes: Sepsis starting point: Mediastinitis or other focus
Another cause of re-admission
_____
Death no
Death Yes:
(Within the first 30 days after discharge)
Cause of death in follow-up: Cardiovascular- NON-cardiovascular cause
_____