

Government of Telangana
Aarogyasri Health Care Trust

CIRCULAR

Circular No. AHCT/P&C Dept. /2016, Date: 03 -11-2016.

Sub: Aarogyasri Health Care Trust – P&C Dept. – Guidelines for S19.2.1 Cadaver Heart Transplantation Surgery under Aarogyasri Scheme – Intimation – Reg.

It is to inform that Trust has included S19.2.1 Cadaver Heart Transplantation Surgery in the listed therapies under S19.2 Heart Transplantation Surgery category under Aarogyasri Scheme. The following are the protocols for S19.2.1 Cadaver Heart Transplantation Surgery under Aarogyasri Scheme.

Protocols for S19.2.1 Cadaver Heart Transplantation Surgery under Aarogyasri Scheme.

I. Indications for Heart transplantation

- > Systolic heart failure (as defined by ejection fraction <35%)
 - a) Inclusive aetiology
 - i. Ischemic
 - ii. Dilated
 - iii. Valvular
 - iv. Hypertensive
 - v. Other
 - b) Excluded aetiology
 - i. HIV infection
 - ii. Cardiac sarcoma
- > Ischemic heart disease with intractable angina
 - i. Ineffective maximal tolerated medical therapy
 - ii. Not a candidate for direct myocardial revascularization, percutaneous revascularization, or transmyocardial revascularization procedure
 - iii. Unsuccessful myocardial revascularization.

- > Intractable arrhythmia
 - a) Uncontrolled with pacing cardioverter defibrillator
 - i. Not amenable to electrophysiology - guided single or combination medical therapy
 - ii. Not a candidate for ablative therapy
- > Intractable arrhythmia
 - b) Class IV symptoms persist despite interventional therapies
 - i. Alcohol injection of septal artery
 - ii. Myotomy and myomectomy
 - iii. Mitral valve replacement
 - iv. Maximal medical therapy
 - v. Pacemaker therapy
- > Congenital heart disease in which severe fixed pulmonary hypertension is not a complication
- > Cardiac tumour
 - i. Confined to the myocardium
 - ii. No evidence of distant disease revealed by extensive metastatic work-up.

II. Absolute Contra indications

- i. Age more than 55 years.
- ii. Irreversible pulmonary hypertension (unresponsive to pharmacologic intervention)
 - a. Pulmonary vascular resistance > 5 Wood units
 - b. Transpulmonary gradient >15 mm Hg
- iii. Active systemic infection
- iv. Active malignancy or history of malignancy with probability of recurrence
- v. Inability to comply with complex medical regimen
- vi. Severe peripheral or cerebro-vascular disease
- vii. Illicit Substance Abuse in last 6 Months
- viii. HIV Positive
- ix. HCV Positive
- x. HBV Positive

III. Relative Contra indications

- i. Recent malignancy
- ii. Chronic obstructive pulmonary disease
- iii. Recent and unresolved pulmonary infarction and pulmonary embolism
- iv. Poorly Controlled DM

- v. Diabetes mellitus with end - organ damage (neuropathy, nephropathy, and retinopathy)
- vi. Active peptic ulcer disease
- vii. Current or recent diverticulitis
- viii. Other systemic illness likely to limit survival or rehabilitation
- ix. Severe osteoporosis
- x. Active alcohol or drug abuse
- xi. History of noncompliance or psychiatric illness likely to interfere with long-term compliance
- xii. Absence of psychosocial support
- xiii. Pan Resistant Respiratory Flora
- xiv. Irreversible dysfunction of another organ including diseases that may limit Prognosis after Transplant, may be considered for multi-organ transplantation.
- xv. Cachexia or Obesity (<70% or >130% of ideal body weight)

IV. Donor Selection Protocols

- > Donor's age should be less than 55 years. '
- > There are three phases of assessment, screening and selection of potential donors.
- > Primary screening
 - It is by procuring agency, factors like Age, Cause of death, Body size, Weight, ABO Group, In-Hospital Course, Viral Profile are all examined.
- > Secondary screening
 - It is by searching for potential contra indications like
 - i. Prolonged cardiac arrest
 - ii. Hypotension
 - iii. Pre-existing cardiac disease (CAG mandatory for the donors above 40 years of age) -
 - iv. Severe chest trauma
 - v. Cardiac injury with raised cardiac enzymes
 - vi. Pre-existing Septicemia
 - vii. Extra cerebral malignancy
 - viii. Presence of Hemo-dynamic instability with high Inotropes.

V. Cardiac Donor Management

- i. First Stage - Volume status, CVP Target 10mm Hg
 - Correct;
 - a. Metabolic acidosis pH 7.4 target,
 - b. Hypoxemia pO₂ > 80mm Hg target,
 - c. Hypercarbia pCO₂ < 35mm, PCV > 30%.
 - Inotropes -to target MAP 60mm Hg.
- ii. Second Stage -
2D Echo study, to rule out Hypertrophy, valvular dysfunction, congenital heart disease, Ideal LVEF > 45% if less put PA Cath and manage and monitor PCWP,
- iii. Third Stage -
Hormonal replacement therapy with T3, Ag vasopressin 1 unit bolus & 0.5 units hourly to achieve SVR 800-1200 dynes, Methyl Prednisolone 1gm, insulin 1 unit with RBS > 80 mg% to target C.I. 2.4 lt/min/mt² BSA within 2 hours.
- iv. All prospective recipients must be prioritised as 1,2,3 as per Jeevandaan priorities and raise pre-authorisation either emergency or elective depending on the condition of the recipient.

IV. Pre-authorisation guidelines

- > **To be raised in two stages**
 - i. Pre-authorisation for investigations:-should submit
 - a) CBP
 - b) CXR
 - c) EGG
 - d) ECHO with colour Doppler
 - e) Serum Creatinine (should be less than 2.5 mg / dL)
 - f) VO₂ to be less than 14 (if not on Beta Blocker)
 - g) Age less than 55 and Proof of Date of Birth
 - h) Height Weight BSA BMI
 - ii. Pre-authorisation for transplant:-
 - (a) Registration with Jeevandan is mandatory
 - (b) Pre-authorisation to be raised by recognized centre and surgical team.

> **Investigations for Recipient**

- i. Serological Tests for HBV, HCV, HIV, CMV, HERPES & TOXOPLASMA
- ii. Cardiac Cath with GAG and calculation OFPA Pressure and / or PVR
- iii. USG Abdomen, HR CT Chest
- iv. Bone Densitometry DEXA Scan of Pelvis and Spine
- v. PFT
- vi. Oxygen Saturation Values at Rest and Exercise
- vii. Coagulation Profile - BT, CT, APTT, PT
- viii. Blood Group RH Type
- ix. C/S of Nasal, Axillary, Groin, Dorsum of Hands for MRSA.
- x. VO₂ values to be documented for recipients, wherever the other criteria for transplant are doubtful.

> **Organ Specific**

- i. PFT
- ii. Blood Urea, Serum Creatinine, EGFR
- iii. Serum Electrolytes
- iv. LFT
- v. Serum Phosphate, Serum Magnesium, Serum Uric Acid

> **Immunological**

- i. Cold and Warm Antibodies, Direct and Indirect Coombs, RA Factor, Anti Cardiolipin Antibody, VDRL
- ii. CMV IgG, IgM and Herpes IgG AND IgM, Anti Hep Antibodies
- iii. ANA Profile
- iv. VZV IgG, IgM
- v. TB PCR in Sputum
- vi. Sputum for AFB
- vii. PRA Class I and II
- viii. If diabetic-HBA1 C
- xi. PSA for males > 50 years
- xii. Vaccination for HBV HAV, FLU Vaccine
- xiii. Peripheral Arterial Doppler Study of Carotid and Limb Vessels
- xiv. Neurology and Psychiatry Consultations

- xv. Cardiology, Nephrology, General Medicine, Gynecology / Urology, Pulmonology, Gastroenterology Consultations, and Dental Checkup, Ophthalmology Consultation for Diabetic and Hypertensive Patients.

VII. Criteria for empanelment of hospitals for carrying out Heart transplant

- i. The hospital should have in-house transplant team to take care of transplant round the dock.
- ii. Should have facilities either in-house or tie-up for pathology, microbiology and biochemistry services to carry out immunological studies and Histopathological studies.
- iii. Should have full time consultants for Radiology, Neurology, Nephrology, Gastroenterology, Pulmonology in addition to transplant team,
- iv. Should have round the dock social worker /grief counsellor.
- v. Hospital shall be registered under Jeevandan - document mandatory.
- vi. High end equipment for 24 hour services like CT Scan, Cath lab, TEE and other imageology studies.
- vii. Should have in-house pharmacy,
- viii. Should have access to well equipped ambulance with driver to transport at short notice night and day.
- ix. 24 hours availability of transplant surgeon / member surgeon at the centre or in the same city / town where he or she can reach quickly is mandatory,
- x. Having an isolation room for managing transplant patient Is mandatory, This is to be staffed with one or two nurses and MNOs / FNOs round the dock exclusively for the patient.

VIII. Transplant Team

- i. Minimum two Cardiothoracic Surgeons ,
- ii. Cardiologist
- iii. Cardiac Anaesthetist
- iv. Transplant Coordinator / Counsellors
- v. Perfusionists
- vi. Nursing Team for Operating Room and ICU ^ ^
- vii. Theatre Assistants
- viii. Administrator

IX. Technical Qualification of Staff

- > Recipient team:
 - i. A cardiac surgeon with recognized qualification and experience of performing cardiac and thoracic operations for at least five years. The second surgeon with recognized qualification with two years experience,
 - ii. Regarding experience of surgeon performing transplant, the surgeon doing regular Open Heart Surgery of 5 years standing will be able to perform technical part of Heart Transplant.
 - iii. A qualified experienced cardiac anaesthetist with five years experience in cardiac surgical team.
 - iv. Two scrub nurses of recognized qualification and experience in cardiac surgery team, one circulating nurse with experience.
 - v. A qualified perfusion technician with recognized bachelor/Diploma in CV perfusion technology with two years experience.
 - vi. A qualified experienced anaesthesia technician.

- > ICU Management:
 - i. A full complement of cardiac surgical intensive care unit consisting of dedicated intensivist / anaesthetist, nurses, technicians, orderlies attending round the clock with qualified specialists on call like Cardiologist, Nephrologists, Pathologist.

X. Post OP Care

- > All transplant patients need lifelong Immunosuppression.
- > They need follow up with CBP, Blood urea, Serum Creatinine, FBS, Echo and ECG with relevant drug levels.
- > Biopsies
 - Heart transplant patients, depending on the clinical situation, will need Endomyocardial Biopsy, up to 8-10 times.

XI. Post Transplant Follow up Protocol

Duration	Frequency of visits
1 st month	Twice a week
2 nd & 3 rd months	Every week
4 th to 6 th month	Twice a month
6 th to 12 th month	Once a month
After 12 th month	Once in 2 months

XII. Immunosuppressant Schedule**ICU AND WARD**

- i. Tacrolimus / Cyclosporine
- ii. Mycophenolate Mofetil / Azathioprim
- iii. Steroids
 - IV Methyl Prednisolone
 - Prednisolone
- iv. Bastliximab - 20 mg IV Day-0 and day-4 / Anti Thymocyte Globulin Injections in case induction is necessary (Extra amount for these drugs with proof of use in case induction is necessary).
- v. Antibiotics - IV and Oral
- vi. Fungal Prophylaxis
 - Clotrimazole
 - Variconazole until 12 Weeks Post Transplant
- vii. Viral Management
 - Gancyclovir alternate days till lines removed.
 - Then Valgancyclovir for 12 weeks of Post Transplant (These two for CMV mismatch)
 - For others Valgancyclovir for 6 Months

NOTE:-The above schedule is indicative and depend on the individual needs to be assessed by the transplant team.

XIII. Postoperative Immunizations

- > Pneumococcal (booster every 5 to 7 years)
- > Influenza A (yearly; centre-specific)
- > Exposure to measles, Varicella, Tetanus, or Hepatitis-B by a non-immunized recipient often warrants specific immunoglobulin therapy (e.g., varicella-zoster immune globulin, VZIG)

XIV. Complications

- > Acute Rejection
- > Acute vascular rejection
- > Infectious complications - may be fungal, viral, bacterial, protozoal.

(For treatment of rejection and infection, separate enhancement should be applied with proof of diagnosis and treatment which will be considered for sanction by CEO).

XV. Chronic Complications

To be applied under the codes existing in NTRVS / EHS.

- i. Chronic allograft vasculopathy
- ii. Renal dysfunction
- iii. Hypertension
- iv. Malignancy

XVI. Drug and Consumables

S.No	Name
1	Betadine irrigation (500ml)
2	Betadine scrub 50ml
3	Cautery Pad
4	Cautery Pencil
5	Drape Sheet (Anti Microbial Incise Each) / loban
6	Elasto Crepe bandage
7	SS wire 20G/2G/28G/30G
8	Surgical Blades no.12
9	Surgical Bladeno.12
10	White Plaster
11	Bone Wax (Each Foil)
12	B.C.D (Blood Cardio Plegia Delivery) Set
13	Custom Tubing Pack
14	Manman Saw Blade
15	Pressure Monitoring Kit
16	Pressure Transducer

17	Oxygenator
18	Cardiplegia Solution 20ml
19	Pressure dome
20	Lead Catheter
21	Disposable Endotracheal
iii.POST OP	
1	White Plaster
iv.PTE SURGICAL	

DISPOSABLES	
i. PRE OP	
1	IV Cannula
2	IV Set
ii. OT	
1	Aortic cannula
2	Disposable ECG Electrodes
3	Disposable Syringes -10CC
4	Disposable Syringes -2ML
5	Disposable Syringes -5ML
6	Dressing Pads
7	Drip Syringes -50ML
8	Extracorpored Blood Circulation Tubing
9	Foleys Bag
10	Foley's Catheter
11	Gloves-Dispoable
12	ICD Bottles (Bags) (Inter Costal Drainage Tubes)
13	ICD Tubes (Inter Costal Drainage Tube)
14	IV Cannula
15	IV Set
16	Pacing wire (Each Foli) (Temporary Cardiac Pacing Wires)
17	Paediatric Drip (Burette set)
18	Pigtail Catheter
19	Radial Artery Cannula
20	Romovac Suction Drain
21	Ryles Tube -Feeding tube
22	Surgical Blades -No-15
23	Suture Nylon 2-0
24	Suture Prolene 6-0
25	Suture Prolene 8-0
26	Suture Vicryl 1-0
27	Suture Vicryl 2-0
28	Stopcock 3-Way
29	Tripple Lumen Catheter
30	Ultra Cardiac Sucker Disposable
31	Umbilical Cotton Tape
32	Venous Extension line with Three was Sterile Disposable-200Cm

33	Ventilator Circuit
	Humid Vent
34	Act Tubes
35	Aortic root cp cannula
36	Cardioplefia retrograde cannula
37	Venous cannula
38	Angiographic catheter -radial
iii.POST OP	
1	Disposable syringes -10CC
2	Disposable syringes-2ML
3	Disposable syringes-5ML
4	Dressing pads
5	Drip syringes -50ML
6	Gloves –disposable
7	ICD bottles (bags) (inter costal drainage tubes)
8	IV Cannula
9	IV Set
iv.POST OP	

C.DRUGS	
i.PRE OP	
1	Ranitidine (rantac)
2	Papaverine
3	Potassium Chloride(kcl)
4	Heparin
5	Aspirin
6	Mecobalamin (B-Complex)
7	Digoxin
8	Furosemide (Diuretics)
9	Torasemide (DYtor)
10	Promethazine (Phenergan)
11	Diazepam
12	Alprazolam / Aplrax
ii. OT	
1	Adrenaline
2	Papaverine
3	Magnesium Sulphate
4	Mannitol
5	Calcium Chloride
6	Potassium Chloride (Kcl)
7	Heparin
8	Tranexamic Acid
9	Transfusion (Double Volume Exchange Blood Transfusion), Blood and Blood Products
10	Dextan (Colloids)
11	NS (IV-Normal Saline)

12	Sodium Bicarbonate (Nahco3)
13	DNS (IV Fluids) (Dextrose)
14	Lingnocaine, Lidocaine (Xyxlocaine, Xylocard)
15	Isoprenaline
16	Noradrenaline (Levarterenol) / Norepinephrine
17	Dopamine
18	Dobutamine
19	Milrinone
20	Nitroglycerin
21	Adenosine
22	Cloxacillin
23	Cefpirome
24	Rocuronium
25	Vasocon
26	Protamine
iii.POST OP	
1	Pantoprazole (Proton Pump Inhibitors (PPI) (Antacids)
2	Papaverine
3	Beclomethasone (Beclate Inaler)
4	Potassium chloride (Kcl)
5	Warfarin
6	Mecobalamin (B-complex)
7	Riconia (Folic acid (vit B12)
8	NS (IV- Normal Saline))
9	Sodium bi carbonate
10	IV R/L (Rringer Lactate)
11	DNS (IV Fluids) (Dextrose)
12	Digoxin
13	Isoprenaline
14	Dopamine
15	Dobutamine
16	Furosemide (Diuretics)
17	Torasemide (Dytor)
18	Spironolactone
19	Enalapril
20	Cloxacillin
21	Cefuroxime /Cefixime (Ceftum)
22	Cefpirome
23	Linezolid
24	DICLOFENAC (Diclofenac Sodium)
25	Rocuumium

*** NOTE:- The above list is only indicative. The choice of various items is left to the Transplant team.**

XVII. Claims attachments

- i. Case Sheet
- ii. Patient on table checking the pre-aesthetic documents
- iii. On table Clinical Photo before induction
- iv. intra OP photos preferably with face
- v. Attachments of the medical Gadgets with monitor with EGG, Pressure wave and saturation.
- vi. Steps of Operation with photo evidence.
- vii. Scar Photo.
- viii. Post OP 2D ECHO, Post OP X Ray. IABP if used, ICU reports, ICU Photos, Critical care Nurse Note, inflow and outflow chart, Co-morbid chart, Post OP PFT, Post OP RFT, ABG report, Blood levels of immunosuppressant and other drugs which are relevant, CBP etc.
- ix. Photo of Transplanted heart beating and EGG pressure monitoring and CVP monitor(recipient)
- x. Photo of Donor heart before implantation. .
- xi. Expenditure incurred in tacking heart from the donor the cardioplegic solution is used. The labels of number of packs used should be photograph and sent.
- xii. The photos of labels of vials of immunosuppressant and anti viral, anti fungal medicine should also be submitted.

XVIII. Donor Heart Transport Protocol

- > Age of donor < 55 years. ^
- > Transport of the organ needs to be carried out at the harvesting centre.
- > The heart needs to be transported in Cardioplegic solution which may cost around Rs.60,000/-.
- > Transportation to be done in a separate box which may cost around Rs.1000/-.
- > The above cost may be included in the package.

All the Network Hospitals shall make a note of the protocols for S19.2.1 Cadaver Heart Transplantation Surgery and follow the guidelines of the Scheme.



Chief Executive Officer

To,

- 1) The MD/CEO/Medical Superintendent of all the Network Hospitals.
- 2) The GM (PMU), AHCT with a request to place in the AHCT Portal.
- 3) The General Manger (FOSS), AHCT with a request to communicate all District Coordinators of the State of Telangana.

Copy to:

All the HoDs of AHCT for favour of information.

The PS to CEO, AHCT for favour of information.