CTSN/CCTRN

LVAD THERAPY: EXPLORING THE EFFECT OF INTRAMYOCARDIAL INJECTION OF MESENCHYMAL PRECURSOR CELLS ON MYOCARDIAL FUNCTION

CASE REPORT FORMS

Date of Birth:	☐☐/☐☐☐/☐☐☐☐ d d m m m y y y y
Sex (check one):	☐ Male ☐ Female

Racial Category (check one):

- ☐ American Indian or Alaska Native
- ☐ Asian
- ☐ Black or African American
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ White

Specify indication for LVAD therapy (check only one):

- ☐ Bridge to Transplantation (BTT)
- ☐ Destination Therapy (DT)

Patient ID: ☐☐☐-☐☐-☐-☐☐☐☐

Blood Chemistry

Parameter	Laboratory Result	Unit of Measure
Date Assessed	☐☐/☐☐☐/☐☐☐☐ (d d m m m y y y y)	
Creatinine	☐☐.☐	mg/dl

Patient ID: ☐☐☐-☐☐-☐-☐☐☐☐

Date Medical History Obtained: ☐☐/☐☐☐/☐☐☐☐
d d m m m y y y y

Cardiovascular History	
Primary Etiology of Heart Failure (Check only one option): ☐ Ischemic ☐ Non-ischemic	
Cardiovascular Procedure History	
Permanent Pacemaker	☐ No ☐ Yes If yes, specify type of pacemaker: ☐ Univentricular pacemaker ☐ Biventricular pacemaker
Current Medical Condition	
Current NYHA Classification: ☐ Class I ☐ Class II ☐ Class IIIa ☐ Class IIIb ☐ Class IV	
Is the patient on an IABP?	☐ No ☐ Yes

Patient ID: ☐☐☐-☐☐-☐-☐☐☐☐

Date of Medication: ☐☐/☐☐☐/☐☐☐☐
d d m m m y y y y

Cardiovascular Therapy	
Beta Blocker	☐ No ☐ Yes
Diuretic	☐ No ☐ Yes
If yes, specify Number of Diuretics:	☐ One ☐ More than one
Aldosterone Receptor Antagonist (i.e. Spironalactone)	☐ No ☐ Yes
Angiotensin Converting Enzyme Inhibitor (ACEi)	☐ No ☐ Yes
Angiotensin II Antagonist (ARB)	☐ No ☐ Yes
Inotropic or Vasoactive Therapy	☐ No ☐ Yes

If yes, type of inotropic or vasoactive therapy (check all that apply):

☐ Dobutamine (Dobutrex) Specify: ☐ Continuous ☐ Intermittent
☐ Milrinone (Primacor) Specify: ☐ Continuous ☐ Intermittent
☐ Nesiritide (Natrecor) Specify: ☐ Continuous ☐ Intermittent
☐ Dopamine Specify: ☐ Continuous ☐ Intermittent
☐ Noradrenaline (Levophed) Specify: ☐ Continuous ☐ Intermittent
☐ Isoprenaline (Isuprel) Specify: ☐ Continuous ☐ Intermittent
☐ Vasopressin (Pitressin) Specify: ☐ Continuous ☐ Intermittent
☐ Other _____ Specify: ☐ Continuous ☐ Intermittent

Patient ID: ☐☐☐-☐☐-☐-☐☐☐☐

Echo Collection: Pre-Implantation

. Test Date: ☐☐/☐☐☐/☐☐☐☐
d d m m m y y y y

Left ventricular end-diastolic diameter:	☐.☐ cm
Left ventricular end-systolic diameter:	☐.☐ cm
LVEF from Simpson's rule:	☐☐☐% ☐ Unable to assess

Patient ID: ☐☐☐-☐☐-☐-☐☐☐☐

Complete within 7 days prior to randomization or in the OR immediately prior to LVAD implantation.

Date of Hemodynamics measured:	☐☐/☐☐☐/☐☐☐☐ (d d m m m y y y y)
Timepoint hemodynamics assessed:	☐ Baseline ☐ Operating Room
Pam	☐☐ mmHg
PCWP	☐☐ mmHg
Cardiac Output	☐☐.☐☐ L/min
Cardiac Index	☐☐.☐ L/min/m^2
PVR	(will be calculated during analysis)

Patient ID: ☐☐☐-☐☐-☐-☐☐☐☐

Treatment Assignment must be administered within 24 hours following Randomization.	
Treatment Assignment:	☐ **Cryopreservation Medium** ☐ **MPC Dose 25M**

Patient ID: ☐☐☐-☐☐-☐-☐☐☐☐

Date of Hospital Admission: ☐☐/☐☐☐/☐☐☐☐ (d d m m m y y y y)

Date of Hospital Discharge: ☐☐/☐☐☐/☐☐☐☐ (d d m m m y y y y)

Reason for admission:

- ☐ Index hospitalization
- ☐ Rehospitalization (specify diagnosis):

Primary Reason for Hospital Admission:

- ☐ Cardiovascular
  - Type of cardiovascular admission:
    - ☐ LVAD related
    - ☐ Non LVAD related
    - ☐ Heart Transplantation
- ☐ Non Cardiovascular

Disposition at hospital discharge:

Patient discharged to:

- ☐ Home
- ☐ Skilled Nursing Care Facility
- ☐ Inpatient Rehabilitation Facility
- ☐ Hospice
- ☐ Death (Complete Mortality form and all other applicable End of Study forms)
- ☐ Other (specify):_____

Patient ID: ☐☐☐-☐☐-☐-☐☐☐☐

Echo Collection

IMMEDIATELY FOLLOWING THE 6 MINUTE WALK	
Test Date: ☐☐/☐☐☐/☐☐☐☐ (d d m m m y y y y)	
Left ventricular end-diastolic diameter:	☐.☐ cm
Left ventricular end-systolic diameter:	☐.☐ cm
LVEF from Simpson's rule:	☐☐☐%

Patient ID: ☐☐☐-☐☐-☐-☐☐☐☐ **Test Date:** ☐☐/☐☐☐/☐☐☐☐
d d m m m y y y y

Was wean attempted?
☐ No. If no, specify _____
☐ Yes

Time Point Minutes	**Is patient weaned from LVAD?**	**Enter any Signs / Symptoms** (check all that apply)
☐ 0 Minute	☐ No ☐ Yes	☐ Asymptomatic ☐ Light Headedness ☐ Dyspnea ☐ Fatigue ☐ Chest Pain ☐ Pulmonary Edema ☐ Other (specify):_____
☐ 1 Minute	☐ No ☐ Yes	☐ Asymptomatic ☐ Light Headedness ☐ Dyspnea ☐ Fatigue ☐ Chest Pain ☐ Pulmonary Edema ☐ Other (specify):_____
☐ 5 Minutes	☐ No ☐ Yes	☐ Asymptomatic ☐ Light Headedness ☐ Dyspnea ☐ Fatigue ☐ Chest Pain ☐ Pulmonary Edema ☐ Other (specify):_____
☐ 10 Minutes	☐ No ☐ Yes	☐ Asymptomatic ☐ Light Headedness ☐ Dyspnea ☐ Fatigue ☐ Chest Pain ☐ Pulmonary Edema ☐ Other (specify):_____
☐ 15 Minutes	☐ No ☐ Yes	☐ Asymptomatic ☐ Light Headedness ☐ Dyspnea ☐ Fatigue ☐ Chest Pain ☐ Pulmonary Edema ☐ Other (specify):_____
☐ 20 Minutes	☐ No ☐ Yes	☐ Asymptomatic ☐ Light Headedness ☐ Dyspnea ☐ Fatigue ☐ Chest Pain ☐ Pulmonary Edema ☐ Other (specify):_____
☐ 25 Minutes	☐ No ☐ Yes	☐ Asymptomatic ☐ Light Headedness ☐ Dyspnea ☐ Fatigue ☐ Chest Pain ☐ Pulmonary Edema ☐ Other (specify):_____
☐ 30 Minutes	☐ No ☐ Yes	☐ Asymptomatic ☐ Light Headedness ☐ Dyspnea ☐ Fatigue ☐ Chest Pain ☐ Pulmonary Edema ☐ Other (specify):_____
☐ 35 Minutes	☐ No ☐ Yes	☐ Asymptomatic ☐ Light Headedness ☐ Dyspnea ☐ Fatigue ☐ Chest Pain ☐ Pulmonary Edema ☐ Other (specify):_____

☐ 40 Minutes	☐ No ☐ Yes	☐ Asymptomatic ☐ Light Headedness ☐ Dyspnea ☐ Fatigue ☐ Chest Pain ☐ Pulmonary Edema ☐ Other (specify):_____
☐ 45 Minutes	☐ No ☐ Yes	☐ Asymptomatic ☐ Light Headedness ☐ Dyspnea ☐ Fatigue ☐ Chest Pain ☐ Pulmonary Edema ☐ Other (specify):_____
☐ 50 Minutes	☐ No ☐ Yes	☐ Asymptomatic ☐ Light Headedness ☐ Dyspnea ☐ Fatigue ☐ Chest Pain ☐ Pulmonary Edema ☐ Other (specify):_____
☐ 55 Minutes	☐ No ☐ Yes	☐ Asymptomatic ☐ Light Headedness ☐ Dyspnea ☐ Fatigue ☐ Chest Pain ☐ Pulmonary Edema ☐ Other (specify):_____
☐ 60 Minutes	☐ No ☐ Yes	☐ Asymptomatic ☐ Light Headedness ☐ Dyspnea ☐ Fatigue ☐ Chest Pain ☐ Pulmonary Edema ☐ Other (specify):_____

Duration of wean: ☐☐☐ Minutes

Patient ID: ☐☐☐-☐☐-☐-☐☐☐☐

Did patient complete 6 Minute Walk?

☐ Yes

If yes, enter distance walked: ☐☐☐☐ feet

☐ No

If no, specify reason

☐ Patient refused

☐ Failed LVAD wean

☐ Other (specify):_____

Test Date: ☐☐/☐☐☐/☐☐☐☐
d d m m m y y y y

Patient ID: ☐☐☐-☐☐-☐-☐☐☐☐

Date of onset:

☐☐/☐☐☐/☐☐☐☐

d d m m m y y y y

Type of Adverse Event Type you are reporting (check one event per form submission):

Expected Adverse Events Related To Intervention

- ☐ **Reaction to Fetal Calf Serum or Murine Mouse Antibody**
- ☐ **Reaction to Dimethyl Sulfoxide**
- ☐ **Potential Study Product Contamination**
- ☐ **Potential Inflammatory Responses**
- ☐ **Possible Effects of Cells on Fetus**

Protocol Defined Adverse Events

☐ **Neoplasm**

Specify Type:_____

☐ **Major Bleeding (not Intra-operative)**

Bleeding resulted in (check all that apply)

- ☐ Blood transfusion greater than or equal to 4 units PRBC within any 24 hour period during the first 7 days post-implant

  If yes, number of units of PRBC ☐☐☐
- ☐ Any transfusion of packed red blood cells (PRBC) within any 24 hour period after 7 days following implant

  If yes, number of units of PRBC ☐☐☐
- ☐ Death
- ☐ Re-operation
- ☐ Re-hospitalization

☐ **Intra-operative Bleeding**

Bleeding resulted in (check all that apply):

- ☐ Blood transfusion >4 units PRBC during an operative event. Specify number of units of PRBC ☐☐☐
- ☐ Re-operation
- ☐ Death

☐ **Cardiac Arrhythmias (specify):**

- ☐ Cardiac arrest
- ☐ Sustained ventricular arrhythmia requiring defibrillation or cardioversion
- ☐ Sustained supraventricular arrhythmia requiring drug treatment or cardioversion
- ☐ Cardiac conduction abnormalities or sustained bradycardia requiring permanent pacemaker placement

☐ **Pericardial Fluid Collection**

Specify clinical intervention

- ☐ Surgical procedure
- ☐ Percutaneous drainage

Were there clinical signs of tamponade? ☐ No ☐ Yes

☐ **Inflammatory Reaction**

Specify reaction

- ☐ Hypersensitivity Reaction
- ☐ Immune Sensitization

☐ **Device Malfunction**

Check type of Device Malfunction / Failure

- ☐ Pump Failure
- ☐ Non-Pump Failure
- ☐ Pump Thrombus, if yes specify ☐ suspected ☐ confirmed

Check all that apply:

☐ Directly caused a state of inadequate circulatory support
☐ Caused death
☐ Iatrogenic or recipient-induced
☐ Manufacturer confirmed device failure

☐ **Hemolysis**

Check clinical signs associated with hemolysis
☐ Anemia
☐ Hyperbilirubinemia (Total Bilirubin > 2mg/dl)
☐ Other (specify):_____

Indicate Plasma Free Hemoglobin (PFH) laboratory values closest to onset of adverse event:

Date of Lab Results ☐☐/☐☐☐/☐☐☐☐ (d d m m m y y y y)

Plasma Free Hemoglobin (PFH) ☐☐☐ mg/dl

☐ **Hepatic Dysfunction**

Were at least two hepatic laboratory values greater than three times the upper limit of normal for the hospital for 1
consecutive days post-implant? ☐ No ☐ Yes

Was hepatic dysfunction the primary cause of death? ☐ No ☐ Yes ☐ N/A

☐ **Hypertension**

Was patient started on anti-hypertensive medication? ☐ No ☐ Yes

☐ **Major Infection (specify):**
☐ Localized Non-Device Infection
☐ Percutaneous Site
☐ Internal Pump Component, Inflow or Outflow Tract Infection
☐ Sepsis
☐ Infectious Myocarditis
☐ Infectious Pericarditis

Cultures obtained? ☐ No ☐ Yes

If yes, specify Organisms and Sites of Infection:

Organism 1: _____ *Site 1:* _____
Organism 2: _____ *Site 2:* _____
Organism 3: _____ *Site 3:* _____

Organism: (Select up to 3 Organisms)

☐ Acinetobacter
☐ Acinobacter baumannii
☐ Aspergillus flavus
☐ Aspergillus versicolor
☐ Asperigillus fumigatus
☐ Bacteroides fragilis
☐ Candida albicans
☐ Candida glabrata
☐ Candida krusei
☐ Citrobacter freundii
☐ Clostridium difficile
☐ Coagulase negative staphylococcus (MRSE)
☐ Corynebacterium striatum
☐ Enterobacter gergoviae
☐ Enterobacter aerogenes
☐ Enterobacter cloacae
☐ Enterococcus faecalis (Vancomycin resistant)
☐ Enterococcus faecalis (Vancomycin sensitive)
☐ Escherichia coli
☐ Klebsiella pneumoniae
☐ Klebsiella oxytoca
☐ Proteus mirabilis
☐ Pseudomonas aeruginosa
☐ Serratia marcescens
☐ Staphylococcus aureus (Methicillin resistant)
☐ Staphylococcus aureus (Methicillin sensitive)
☐ Staphylococcus epidermididis (Methicillin resistant)
☐ Staphylococcus epidermididis (Methicillin sensitive)
☐ Stenotrophomas
☐ Streptococcus
☐ Torulopsis glabrata
☐ Viridans strep
☐ Other organism
Specify Other:_____

Site: (Select up to 3 Sites)
- ☐ Blood
- ☐ Catheter

Specify catheter type: _____
- ☐ VAD driveline exit site
- ☐ VAD inflow or outflow tract
- ☐ VAD valve
- ☐ VAD pump pocket
- ☐ Nares
- ☐ Oral mucosa
- ☐ Pharynx
- ☐ Pleural Fluid
- ☐ Rectal mucosa
- ☐ Rectum
- ☐ Skin
- ☐ Sputum
- ☐ Stool
- ☐ Tracheotomy site
- ☐ Urine
- ☐ Wound/Drainage

  Specify drainage: _____
- ☐ Other

  Specify: _____

☐ **Myocardial Infarction - Perioperative**

Check criteria (all three have to be present to be classified as a perioperative MI)
- ☐ Clinical suspicion of MI
- ☐ CK-MB or Troponin > 10 x ULN
- ☐ ECG consistent with acute MI

☐ **Myocardial Infarction - Non-perioperative**

Check criteria (two of three have to be present to be classified as a non-perioperative MI)
- ☐ Chest pain
- ☐ ECG with a pattern or changes consistent with a myocardial infarction
- ☐ Troponin or CK greater than the normal range with positive CK-MB

☐ **Myocardial Rupture**

With hemodynamic instability? ☐ No ☐ Yes

Presence evidenced by
- ☐ Direct visualization
- ☐ Echo
- ☐ Ventriculography
- ☐ Other (specify):_____

☐ **Neurological Dysfunction**
- ☐ Transient Ischemic Attack -TIA
- ☐ Ischemic Stroke - CVA
- ☐ Hemorrhagic Stroke - CVA
- ☐ Toxic Metabolic Encephalopathy
- ☐ Other Neurological Dysfunction (specify):_____

☐ **Psychiatric Episode**

☐ **Acute Renal Dysfunction**

☐ **Chronic Renal Dysfunction**

Did the patient require dialysis? ☐ No ☐ Yes If yes, specify type ☐ CVVH ☐ HD ☐ PD

☐ **Respiratory Failure**

☐ **Right Heart Failure** (Specify Intervention required to treat the signs and symptoms of RHF):
- ☐ RVAD implantation
- ☐ Intravenous inotropic therapy
- ☐ Inhaled nitric oxide

Check all signs/symptoms that apply(At least one box should be checked)
- ☐ CVP > 18 mmHg
- ☐ CI < 2.0 L/min/m2
- ☐ Ascites
- ☐ Peripheral Edema

☐ **Arterial Non-CNS Thromboembolism,** specify location:
- ☐ Renal
- ☐ Hepatic
- ☐ Splenic
- ☐ Bowel
- ☐ Limb
- ☐ Other (specify):_____

☐ **Venous Thromboembolism Event,** specify location:
- ☐ Deep vein thrombosis
- ☐ Pulmonary embolism
- ☐ Other (specify): _____

☐ **Wound Dehiscence**

☐ **Vasodilatory State**

☐ **Unexpected Other Serious Adverse Event**, specify: _____

5. Seriousness of Adverse Event

Seriousness of Adverse Event
- ☐ Serious (If serious, notify DCC immediately)
- ☐ Not Serious

If this is a serious adverse event, specify reasons (check all that apply)
- ☐ Fatal
- ☐ Life threatening
- ☐ Results in permanent disability
- ☐ Requires hospitalization
- ☐ Prolongs hospital stay

Patient ID: ☐☐☐-☐☐-☐-☐☐☐☐

Date of Study Completion/Early Termination: ☐☐/☐☐☐/☐☐☐☐
d d m m m y y y y

Choose primary reason for completion or early termination (check one):

☐ Heart Transplantation,

If Heart Transplantation checked, enter start time of anesthesia (24 hour clock): ☐☐:☐☐

☐ Study Completion at 12 months post randomization

☐ Death. Complete mortality form.

☐ Investigator decision to withdraw patient. Explain:_____

☐ Patient withdrawal of consent. Explain:_____

☐ Other. Explain:_____

Patient ID: ☐☐☐-☐☐-☐-☐☐☐☐

Date of Death: ☐☐/☐☐☐/☐☐☐☐

d d m m m y y y y

Patient ID: ☐☐☐-☐☐-☐-☐☐☐☐

Adverse Event ID# ☐☐☐

Patient ID: ☐☐☐-☐☐-☐-☐☐☐☐

ADVERSE EVENT ADJUDICATION

Date of Adjudication	☐☐/☐☐☐/☐☐☐☐ d d m m m y y y y
Overall Event Assessment	☐ Agree with Adverse Event Classification ☐ Disagree with Adverse Event Classification ☐ Not a Serious or Protocol Defined Adverse Event ☐ Secondary Manifestation of a Previously Reported Adverse Event: Specify AEID ☐☐☐ ☐ Need Additional Information to Adjudicate Adverse Event: List additional information required _____

Seriousness of Adverse Event
☐ Agree with Seriousness of Adverse Event Classification
☐ Disagree with Seriousness of Adverse Event Classification If Disagree, Reclassify: ☐ Serious ☐ Not Serious If reclassified as serious, check all that apply: ☐ Fatal ☐ Life threatening ☐ Results in permanent disability ☐ Requires hospitalization ☐ Prolongs hospital stay
☐ Need Additional Information to Adjudicate Seriousness of Adverse Event Classification List Additional Information Required: _____

AE Reclassification	
1.	☐ Reaction to Fetal Calf Serum or Murine Mouse Antibody
2.	☐ Reaction to Dimethyl Sulfoxide
3.	☐ Potential Study Product Contamination
4.	☐ Potential Inflammatory Responses
5.	☐ Possible Effects of Cells on Fetus
6.	☐ Neoplasm
7.	☐ Major Bleeding (non-intraoperative)
8.	☐ Intraoperative Bleeding
9.	☐ Cardiac Arrhythmias-Cardiac arrest
10.	☐ Cardiac Arrhythmias-sustained ventricular arrhythmia requiring defibrillation or cardioversion
11.	☐ Cardiac Arrhythmias-sustained supraventricular arrhythmia requiring drug treatment or cardioversion
12.	☐ Cardiac conduction abnormalities or sustained bradycardia requiring permanent pacemaker placement
13.	☐ Pericardial Fluid Collection
14.	☐ Inflammatory Reaction- Hypersensitivity Reaction
15.	☐ Inflammatory Reaction- Immune Sensitization
16.	☐ Device Malfunction -Pump Failure
17.	☐ Device Malfunction -Non-Pump Failure

18.	☐ Device Malfunction -Pump Thrombus-suspected
19.	☐ Device Malfunction -Pump Thrombus-confirmed
20.	☐ Hemolysis
21.	☐ Hepatic Dysfunction
22.	☐ Hypertension
23.	☐ Major Infection-Localized Non-Device Infection
24.	☐ Major Infection- Percutaneous Site
25.	☐ Major Infection-Internal Pump Component Inflow or Outflow Tract Infection
26.	☐ Major Infection-Sepsis
27.	☐ Major Infection- Infectious Myocarditis
28.	☐ Major Infection-Infectious Pericarditis
29.	☐ Myocardial Infarction-Perioperative
30.	☐ Myocardial Infarction-Non-perioperative
31.	☐ Myocardial Rupture
32.	☐ Neurological Dysfunction-TIA
33.	☐ Neurological Dysfunction-Ischemic Stroke
34.	☐ Neurological Dysfunction-Hemorrhagic Stroke
35.	☐ Neurological Dysfunction-Toxic Metabolic Encephalopathy
36.	☐ Neurological Dysfunction-Other, specify: _____
37.	☐ Psychiatric Episode
38.	☐ Renal Dysfunction-Acute
39.	☐ Renal Dysfunction-Chronic
40.	☐ Respiratory Failure
41.	☐ Right Heart Failure
42.	☐ Arterial Non-CNS Thromboembolism
43.	☐ Venous Thromboembolism Event
44.	☐ Wound Dehiscence
45.	☐ Vasodilatory State
46.	☐ Other Serious Adverse Event, specify: _____