Study protocol cover page

Official study title: Multicenter registry to study the characteristic and outcomes of Jordanian Heart Failure patients

The Jordanian Heart Failure Registry (JoHFR)

NCT04829591

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A Multicenter Registry to Study the Characteristics and Outcomes of Jordanian Heart Failure Patients.

The Jordanian Heart Failure Registry (JoHFR)

ClinicalTrials.gov Identifier: NCT04829591

(Study protocol)

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Brief Summary

Heart Failure research registry is a collection of computerized information about individuals with heart failure. The database in this registry is obtained from several Jordanian medical centers which will represent an extremely valuable resource for epidemiological research on heart failure patients.

Detailed Description:

Understanding the cause of Heart Failure (HF) and how the body will respond to it, is critical for an effective treatment. HF is a global problem with significant morbidity and mortality, despite improved understanding of the pathophysiology and a growing range of therapeutic options. Jordanian Heart Failure Registry (JoHFR) will be the first research project of heart failure prevalence in Jordan. It is undertaken by primary healthcare professionals with main aim to improve knowledge about the care of patients with HF. The investigators responsible for conducting this research are physicians and their teams who deal with heart failure patients in their outpatient and inpatient clinic centers including the public and private medical sectors in Jordans' medical community . Standards in the Hashemite kingdom of Jordan complies with the recognized good guideline directed medical practices internationally.

Objectives of the registry:

Up to date, there is still a lack of reliable pathology data that summarizes patient cases with heart failure disease. This research aims to fill this gap and provide the local and international medical communities with this important set of comparative data in order to determine our current situation in regards to screening, management, and follow up of patients. This will have a direct impact on improving Heart Failure patient outcomes by directing our focus on strengths and weaknesses in our management in this ongoing high morbidity and mortality syndrome. Furthermore, this registry will focus on describing the diagnostic and therapeutic approaches undertaken by cardiologists in their care of patients with HF in order to improve future management

of patients with high HF risks. The prevalence of the clinical profiles of patients with acute and chronic HF will also be evaluated.

Study design and methodology:

- This registry consists of multiple variables including demographics, concomitant diseases, diagnostic procedures, hemodynamics, laboratory data, and medications used, discharge information and instructions. The patient information is detailed in the attached questionnaire (appindex1) which will be filled by participating who will record details of their HF patients and transfer these data for documentation.
- This study aims to include sufficient number of patients with Heart Failure and is expected to last for extended time until the study sample is completed by participating healthcare professionals. The data collected at 12 months will be the basis of the initial statistics, upon which the trial duration will be determined.
- The principal research coordinator and his team will train personnel of the participating units on how to register patients and how to use the registry.
- Patient safety, security and confidentiality will be retained at all times during the course of the study and thereafter.
- Follow up after one year should include data on morbidity (including Heart failure hospitalization) and mortality with detailed information on medications, quality of life, and functional capacity. ▪ The study will comply with the ethics of research and (IRB) institutional review board approvals and any other required official organizational requirements.

Inclusion and exclusion criteria:

- ***Inclusion criteria:***
  1. Patients who are 18 years or older with Heart Failure diagnosis as defined by internationally recognized guidelines.
  2. Current residents of the Hashemite Kingdom of Jordan.
- ***Exclusion criteria:***
  1. Patients who refuse or unable to sign a consent form.
  2. Patient inability to follow up with provider

Statistical analysis:

Data will be pooled and descriptive and comparative statistical tests will be used to categorize the patients based on the disease sub-typing and management quality and to find the prevalence of heart failure disease different types, classes and stages amongst Jordanians. Furthermore, comparative analysis will be performed to test the efficiency, accuracy, and the quality of medical practice in Jordan. Statistical analysis will be done using SPSS V21.

See appindex1 below.

Appindex1:

Chronic HF ☐ Acute HF ☐	**Patient Initials/Site number:**
DOB: / / (MM/DD/YYYY) Gender: M F **Admission date/ Office visit** / / :	
Discharge Date/Time / / :	

Medical History (Select all that apply):

□ H/O ASCVD □ H/O Arrhythmias □ ASCVD risk factor: •• DM •• HTN •• Smoking •• Alcohol Abuse •• Dyslipidemia •• Obesity •• Positive family history of premature ASCVD •• CKD •• Others.	□ Implanted devices □ History of structural heart disease □ Other relevant medical history	❑ Notes :
Heart Failure History		
Etiology: **Check if history of :**	□ Ischemic/CAD	❑ Non-Ischemic □ Hypertensive □ Alcohol/Other Drug □ Chemotherapy □ Viral □ Postpartum
		□ Familial □ Other Etiology □ Unknown/Idiopathic

Known history of HF prior to this admission?	○ Yes	○ No

# of hospital admissions in past 6 mo./office visit for HF:	0 1 2 >2	○ Unknown
Medications Used Prior to Admission: *[Select all that apply]*		

❑ Patient on no meds prior to admission ❑ ACE Inhibitor ❑ Aldosterone Antagonist ❑ Angiotensin receptor blocker (ARB) ❑ Angiotensin Receptor Neprilysin Inhibitor (ARNI) ❑ Antiarrhythmic ❑ Aspirin ❑ Antiplatelet agent (excluding aspirin)	❑ Anticoagulation Therapy ○ Warfarin ○ **Direct Thrombin Inhibitor**(dabigatran) ○ **Factor Xa Inhibitor**(apixaban, rivaroxaban, edoxaban) ○ Other ❑ Anti-hyperglycemic medications: □ **DPP-4 Inhibitors**(sitagliptin, vildagliptin, saxagliptin, linagliptin, alogliptin) □ **GLP-1 receptor agonist** (liraglutide, albiglutide, exenatide, semaglutide) □ Insulin □ Metformin □ **SLGT2 Inhibitor** (canagliflozin, dapagliflozin, empagliflozin, ertuglifluzin) □ Sulfonylurea(glibenclamide, glimperide, glipizide, tolbutamide) □ Thiazolidinedione(pioglitazone, rosiglitazone) □ Other Oral Agents □ Other injectable/subcutaneous agents	❑ Beta-Blocker(metoprolol, propranolol, bisoprolol, atenolol, acebutelol, nebivelol, nadolol) ❑ Ca channel blocker(amlodipine, nefidipine, nicardipine, verapamil, diltiazem) ❑ Digoxin ❑ Diuretic □ Thiazide/Thiazide like(chlorothalidone, hydrochlorothiazide, indapamide, metolazone) □ Loop(bumetanide, furosemide, torsemide) ❑ Hydralazine ❑ Ivabradine ❑ Lipid lowering agent (Any) □ Statin(rosuvastatin, atorvastatin, simvastatin, fluvastatin, pravastatin) □ Other Lipid lowering agent ❑ Nitrate(nitroglycerin, nitroprusside, isosorbide) ❑ Other

Symptoms (Closest to Admission) *Select all that apply*	❑ Dyspnea NYHA class **(I, II, III, IV)** ❑ Orthopnea ❑ PND ❑ Fatigue ❑ Chest pain	❑ Palpitations

Vital signs	**Height ��** cm

(Closest to Admission/Office visit)	**Weight BMI ��** Kgs.

Heart Rate	**Heart Rate** bpm	❑ Regular ❑ irregular	
Examination (Closest to Admission/Office visit)	JVP: ○ Yes	○ No	
	Rales: ○ Yes	○ No	
	Lower Extremity Edema ○ Yes	○ No	
Lipids	TC: LDL: HDL: _ mg/dL mg/dL mg/dL	TG: mg/dL	❑ Lipids Not Available
Labs Closest to Admission)/ office visit	Na	○ mg/dL	❑ Unavailabl e
	BNP	○ ng/L	❑ Unavailabl e
	K	○ mg/dL	❑ Unavailabl e
	Hb	○ g/dL	❑ Unavailabl e
	Albumin	○ g/dL	❑ Unavailabl e
	NT-proBNP	○ ng/L	❑ Unavailabl e
	SCr	○ mg/dL	❑ Unavailabl e

	eGFR	○ ml/min/ 1.73m^2	❑ MDRD
	BUN	○ mg/dL	❑ Unavailabl e
	Troponin (Peak) ng/L ⬚⬚ T quantitative / Hs ⬚⬚ I	⬚⬚ Normal ⬚⬚ Abnormal	❑ Unavailabl e
	Ferritin ng/mL Transferrin saturation		
	HbA1C %	Unavailable	

	Fasting Blood Glucose (mg/dL)	Unavailable
	EKG QRS	Unavailable

	Duration (ms)	
	EKG QRS ⬚⬚ Normal ⬚⬚ RBBB ⬚⬚ LBBB ⬚⬚ NS IVCD Morphology	⬚⬚ Paced ⬚⬚ Unavailable
Procedures		

❑ No Procedures

❑ Cardiac Cath/Coronary Angiography

❑ Coronary Artery Bypass Graft

❑ CRT-P (cardiac resynchronizationtherapy pacing only)

❑ Dialysis or Ultrafiltration

❑ ICD only

❑ Mechanical Ventilation

❑ PCI

❑ Right Cardiac Catheterization

❑ Atrial Fibrillation Ablation or Surgery

❑ Cardiac Valve Surgery

❑ Cardioversion

❑ CRT-D (cardiac resynchronization therapy with ICD ❑ Intra-aortic Balloon Pump

❑ Left Ventricular Assist Device

❑ Pacemaker

EF	- By Echo - By other means %	Obtained:	❑❑ This Admission ❑❑ Within the last year ❑❑ > 1 year ago
Added Oral Medications during hospitalization *Select all that apply*	❑ None ❑ ARNI ❑ ARB	❑ Aldosterone Antagonist ❑ Hydralazine Nitrate	❑ ACE Inhibitor ❑ Beta Blocker
Parenteral Therapies during hospitalization *Select all that apply*	❑ None ❑ Dopamine ❑ Iron ❑ Milrinone	❑ Nitroglycerine ❑ Other IV Vasodilator	❑ Dobutamine ❑ Loop Diuretics □ Intermittent Bolus □ Continuous Infusion

Was the patient ambulating at the end of hospital day 2?	Yes No	Not Documented

Was DVT prophylaxis initiated by the end of hospital day 2?	Yes No	Contraindicated

If yes,	❑ Low dose unfractionated heparin (LDUH) ❑ Low molecular weight heparin (LMWH) ❑ Warfarin ❑ Other	❑ Factor Xa Inhibitor ❑ Direct thrombin inhibitor ❑ Intermittent pneumatic compression devices (IPC)
Discharge Date/Time / / :		❑ MM/DD/YYYY only
Primary Cause of Death	○ Cardiovascular ○ Non-Cardiovascular	○ Unknown
If Cardiovascular:	○ Acute Coronary Syndrome ○ Worsening Heart Failure	○ Sudden Death ○ Other
When is the earliest documentation of comfort measures only?	○ Day 0 or 1 ○ Day 2 or after	○ Timing unclear ○ Not Documented

Symptoms (closest to discharge)	○ Worse ○ Unchanged ○ Better, Symptomatic ○ Better, Asymptomatic	○ Unable to determine
Vital Signs (closest to Discharge)	Weight ⬜⬜Kgs.	❑ Not Documented
	Heart Rate Bpm regular Irregular	❑ Not Documented
	BP-Supine _ / _ mmHg (systolic/diastolic)	❑ Not Documented
	Respiratory Rate breaths per minute	
Exam (Closest to Discharge)	JVP: ○ Yes ○ No	○ Unknown
	Rales: ○ Yes	○ No

	Lower Extremity Edema ○ Yes	○ No	
Labs (Closest to Discharge)	Na	○ mg/dL	❑ Unavailable

	BNP	○ mg/dL	❑ Unavailable
	SCr	○ mg/dL	❑ Unavailable
	BUN	○ mg/dL	❑ Unavailable
	NT-BNP (pg/mL)	❑ Not Documented	
	K ○ mEq/L	○ mmol/L	○ mg/dL ❑
	eGFR	◆◆ Ml/min/ 1.73m^2	❑ MDRD

Angiotensin Converting Enzyme Inhibitor (ACEI)		
Prescribed? If Yes,	○ Yes ○ No Medication: Dosage:	Frequency:
Beta-Blocker		

Name:	Dose:	
Aldosterone Antagonist		
	Medication: Dosage:	Frequency:
Anti-hyperglycemic Medications:		
Name:	Dose:	
Lipid Lowering Medication(s):		
Name:	Dose:	
Hydralazine Nitrate		

Name:	Dose:	
Other Medications at Discharge		
❑ Antiarrhythmic □ Amiodarone □ Sotalol □ Other	❑ Ca Channel Blocker ❑ Digoxin ❑ Diuretic □ Loop Diuretic □ Thiazide Diuretic	❑ Nitrate ❑ Ranolazine ❑ Other Anti-Hypertensive ❑ Other

Angiotensin Receptor Blocker (ARB)		
Name:	Dose:	
Angiotensin Receptor Neprilysin Inhibitor (ARNI)		
Name:	Dose:	
Acetylsalicylic acid (ASA)		
Name:	Dose:	
Anticoagulation Therapy		
Prescribed?	Yes No	Dosage
If Yes,	**Class:** ❑ Other	

	❑ Warfarin	

	❑ DOAC	
Clopidogrel		
Prescribed?	○ Yes ○ No	

If Yes,	Dosage: Frequency:		
Other Antiplatelet(s)			
Name:	dose:		
Activity	○ Yes ○ No Diet (Salt restricted)	○ Yes	○ No
Follow-up Symptoms Worsening	○ Yes ○ No Medications ○ Yes ○ No Weight Monitoring	○ Yes ○ Yes	○ No ○ No
Follow-up Visit Scheduled	○ Yes ○ No **Date/Time of first follow up visit:**	/ / :	
Location of first follow-up visit: ◆◆ Office Visit ◆◆ Home Health Visit		◆◆ Telehealth ◆◆ Not Documented	

Medical or Patient Reason for no follow-up appointment being scheduled?	○ Yes	○ No
Follow up visits form:		
Scheduled at:	3 months 6 months	12 months
NYHA class: (I,II,III,IV)		

eGFR:		
Loop diuretics (name,dose):		
Vital signs		
New EF ,method, if any :		
CV related hospital admission:	❑ Yes: □ WHF □ ACS □ Arrhythmia s □ Others	❑ Yes: □ WHF □ ACS □ Arrhythmia s □ Others
	❑ Yes: □ WHF □ ACS □ Arrhythmias □ Others No **12 months**	

	No No **3 months 6 months**	

Labs:		
Meds:		

Other notes:		