PVP-Guided Decongestive Therapy in HF 2 (PERIPHERAL-HF2) NCT06495892

July 1st, 2024

PERIPHERAL-HF Page 1

Identification

Project ID#		
Name and surname		
National ID#		
Age		
Gender	○ Male ○ Female	
Boy (in centimeters)		
Kilo (the first measured weight in kilograms)		
Recommend allowing access for physicians to e-pulse account. (For easy access to long-term follow-up).		
Phone number (May be required for follow-up. Example; 0532 510 97 98, 0216 283 38 38)		
Phone number #2 (if available) (May be required for follow-up. Example; 0532 510 97 98, 0216 283 38 38)		

Randomization

Center	🔿 Ankara Etlik Şehir Hastanesi
(Please select randomizing center.)	 Antalya Atatürk Devlet Hastanesi Akdeniz Üniversitesi Tıp Fakültesi Bağcılar Eğitim ve Araştırma Hastanesi Bakırçay Üniversitesi Tıp Fakültesi, Çiğli Eğitim ve Araştırma Hastanesi Başakşehir Çam ve Sakura Şehir Hastanesi Dr. Siyami Ersek Göğüs Kalp ve Damar Cerrahisi Eğitim Ve Araştırma Hastanesi Eskişehir Şehir Hastanesi Eskişehir Şehir Hastanesi Erzurum Atatürk Üniversitesi Hastanesi İdil Devlet Hastanesi Kafkas Üniversitesi Sağlık Araştırma ve Uygulama Hastanesi Kütahya Sağlık Bilimleri Üniversitesi Tıp Fakültesi Hastanesi Mehmet Akif Ersoy Eğitim ve Araştırma Hastanesi Tokat Gaziosmanpaşa Üniversitesi Tıp Fakültesi Hastanesi Trakya Üniversitesi Tıp Fakültesi Hastanesi
Study arm (Study arm according to randomization scheme)	 Pressure guided Standard
Randomization date (Select as day-month-year)	
Has the patient been excluded? (Has the patient been excluded after randomization ?)	○ Yes ○ No
Select the reason for exclusion. (Select the reason for exclusion if the patient has been excluded after randomization.)	 □ Upper extremity venous disease □ Serum creatinine ≥ 3.5 mg/dL □ Severe stenotic valvular disease □ Hypertrophic obstructive cardiomyopathy □ Rejection or withdrawal of consent □ Other
Please explain. (Explain the reason for exclusion if the patient has been excluded after randomization.)	
Consent form (You can download consent form from this link.)	
[Attachment: "PERIPHERAL-HF Onam formu.pdf"]	
Signed consent form	

(Please upload scanned file or photo of signed consent form. Keep the original.)



History

Project ID#		
Hypertension (Average blood pressure >140/90 mmHg or use of antihypertensive medication)	⊖ Yes	⊖ No
Diabetes (FPG>126 mg/dL for two times or HbA1c>%6.5 or use of antidiabetic medication)	⊖ Yes	⊖ No
Dyslipidemia	⊖ Yes	○ No
(LDL>160 mg/dL or use of antihyperlipidemic drug)		
Active smoking (Smoking history in the last one year)	⊖ Yes	⊖ No
Chronic obstructive pulmonary disease (Prior diagnosis of COPD or long-acting bronchodilator use with a clinical picture consistent with COPD)	⊖ Yes	⊖ No
Chronic kidney disease (GFR < 60 ml/min/1.73 m2 known or supposed to be longer than 3 months)	⊖ Yes	⊖ No
Prior myocardial infarct (Documented diagnosis or imaging evidence of an old [>1 month] myocardial infarct)	⊖ Yes	⊖ No
Prior percutaneous coronary intervention	⊖ Yes	⊖ No
(Documented history or imaging evidence of a prior coronary intervention)		
Prior coronary arterial by-pass grafting (Documented history or imaging evidence of a prior CABG)	⊖ Yes	⊖ No
Prior ICD/CRT implantation (Documented history or imaging evidence of a prior ICD/CRT implantation)	⊖ Yes	⊖ No



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Admission Findings

Admission type (With regard to heart failure)	 De novo heart failure Heart failure decompensation
Etiology of heart failure (Respond accoerding to current or past information.)	 Ischemic Non-ischemic Could not be differentiated
Systolic blood pressure on admission (in mmHg)	
Heart rate on admission (in beats per minute)	
Subjective dyspnea score	
 Rare Frequent Always 	
Subjective orthopnea score	
 None Rare Frequent Always 	
Subjective fatigue score	
 None Rare Frequent Always 	
Pretibial edema	
 ○ None ○ 1+ ○ 2+ ○ 3+ ○ 4+ 	
Pulmonary rales	
 None Limited to the bases Lower half More than lower half 	



Jugular venous distention

(Compared to angle of Louis while lying at 45 degree supine position.)

 Cannot be observed Normal (< 4.5 cm) High (>4.5 cm) but pulsations can be seen Exceeds angulus mandibula 	
BUN on admission (Just before or after admission, in mg/dL, e.g.; 12)	
Creatinine on admission (Just before or after admission, in mg/dL, e.g.; 1.2)	
Sodium on admission (Just before or after admission, in mEq/L, e.g.; 142)	
Potassium on admission (Just before or after admission, in mEq/L, e.g.; 4.2)	
Hemoglobin on admission (Just before or after admission, in g/dL, e.g.; 12.3)	
Hematocrit on admission (Just before or after admission, in %, e.g.; 31)	
Albumin on admission (Just before or after admission, in g/dL, e.g.; 3.1)	
Total protein on admission (Just before or after admission, in g/dL, e.g.; 5.2)	
BNP/NT-proPNP on admission (Just before or after admission, in pg/mL, e.g.; 125)	
Uric acid on admission (Just before or after admission, in mg/dL, e.g.; 5.5)	
Rhythm on ECG ? (Dominant rhythm on ECG')	 Sinus AF Other
Left bundle branch block on ECG ? (Select according to the dominant conduction, excluding pacemaker rhythm)	○ Yes ○ No
Ejection fraction (in percent, example; 55)	
Mitral regurgitation (0=none, 1=mild, 2=moderate, 3=moderate-to-severe, 4=severe)	



Tricuspid regurgitation (0=none, 1=mild, 2=moderate, 3=moderate-to-severe, 4=severe)

Estimated pulmonary arterial pressure (in mmHg including estimated right atrial pressure, e.g.; 50. 0 if cannot be calculated.)

Venous pressure

(in mmHg; e.g., 5. If the subject is in standard therapy arm, caregiver should be blinded to this measurement.)

Quality of waveform

(Interpret the visual quality of waveform)

- Good (Clear atrial or respiratory pressure oscillations)
- Moderate (Less clear pressure oscillations but a stable measurement with an appropriate modified-Valsalva response)
- Poor (No oscillations, increasing, no appropriate modified-Valsalva response or nonphysiological readings)

Prior Medications

Aspirin (Used medications before admission)	⊖ Yes	⊖ No
P2Y12 inhibitor (Used medications before admission)	() Yes	○ No
OAC/NOAC (Used medications before admission)	() Yes	○ No
Beta-blocker (Used medications before admission)	() Yes	○ No
ACEi/ARB (Used medications before admission)	() Yes	⊖ No
ARNI (Used medications before admission)	⊖ Yes	⊖ No
SGLT2i (Used medications before admission)	⊖ Yes	⊖ No
MRA (Used medications before admission)	⊖ Yes	⊖ No
Loop diuretic (Used medications before admission)	() Yes	⊖ No
Oral furosemide equivalent dose (40 mg furosemide po=20 mg furosemide iv=20 mg torasemide po)		
Digoxin (Used medications before admission)	() Yes	⊖ No
Statin (Used medications before admission)	⊖ Yes	⊖ No

In-hospital Course (1st day)

1st day fluid intake	
(From admission to next day morning, in mL , e.g.; 1250)	
1st day urine output	
(From admission to next day morning, in mL , e.g.; 1250. Do not add extra losses, such as paracentesis or thoracentesis)	
BUN after 1st day	
(First morning value after admission, in mg/dL , e.g.; 25)	
Creatinine after 1st day	
(First morning value after admission, in mg/dL , e.g.; 1.5)	
Sodium after 1st day	
(First morning value after admission, in mEq/L , e.g.; 135)	
Potassium after 1st day	
(First morning value after admission, in mEq/L , e.g.; 4.5)	
Total intravenous furosemide equivalent of loop diuretic dose (40 mg furosemide po=20 mg furosemide iv=20 mg torasemide po)	
Total asetozolamide dose (0 if not used)	
Total thiazide dose (0 if not used)	
Total MRA dose (0 if not used)	
1st day venous pressure	
(Value in the first morning after admission, in mmHg, e.g.,: 25)	

e.g..; 25)

Quality of waveform	 Good (Clear atrial or respiratory pressure oscillations)
(Interpret the visual quality of waveform)	 Moderate (Less clear pressure oscillations but a stable measurement with an appropriate modified-Valsalva response) Poor (No oscillations, increasing, no appropriate modified-Valsalva response or nonphysiological readings)
You do not need to input any data in this form as the in-hospital follow-up is ended. Please proceed to the next instrument . (If in-hospital follow-up continues, check the previous form "Discharged today (or follow-up is terminated for another reason) ? and change the answer to "No".)	○ Yes ○ No



In-hospital Course (2nd day)

2nd day fluid intake	
(From previous to this day morning, in mL , e.g.; 1250)	
2nd day urine output	
(From previous to this day morning, in mL , e.g.; 1250. Do not add extra losses, such as paracentesis or thoracentesis)	
BUN after 2nd day	
(First morning value after admission, in mg/dL , e.g.; 25)	
Creatinine after 2nd day	
(First morning value after admission, in mg/dL , e.g.; 1.5)	
Sodium after 2nd day	
(First morning value after admission, in mEq/L , e.g.; 135)	
Potassium after 2nd day	
(First morning value after admission, in mEq/L , e.g.; 4.5)	
Total intravenous furosemide equivalent of loop diuretic dose	
(40 mg furosemide po=20 mg furosemide iv=20 mg torasemide po)	
Total asetozolamide dose (0 if not used)	
Total thiazide dose (0 if not used)	
Total MRA dose (0 if not used)	
2nd day venous pressure	
(Value in the second morning after admission, in mmHg,	



Quality of waveform	 Good (Clear atrial or respiratory pressure oscillations)
(Interpret the visual quality of waveform)	 Moderate (Less clear pressure oscillations but a stable measurement with an appropriate modified-Valsalva response) Poor (No oscillations, increasing, no appropriate modified-Valsalva response or nonphysiological readings)
Discharged today (or follow-up is terminated for another reason) ?	○ Yes ○ No
(If "Yes" these values will be accepted as pre-discharge measurements.)	



In-hospital Course (3rd day)

3rd day fluid intake	
(From previous to this day morning, in mL , e.g.; 1250)	 -
3rd day urine output	
(From previous to this day morning, in mL , e.g.; 1250. Do not add extra losses, such as paracentesis or thoracentesis)	-
BUN after 3rd day	
(Third morning value after admission, in mg/dL , e.g.; 25)	 -
Creatinine after 3rd day	
(Third morning value after admission, in mg/dL , e.g.; 1.5)	 -
Sodium after 3rd day	
(Third morning value after admission, in mEq/L , e.g.; 135)	 -
Potassium after 3rd day	
(Third morning value after admission, in mEq/L , e.g.; 4.5)	 -
Total intravenous furosemide equivalent of loop	
diuretic dose (40 mg furosemide po=20 mg furosemide iv=20 mg torasemide po)	 -
Total asetozolamide dose (0 if not used)	 -
Total thiazide dose (0 if not used)	 -
Total MRA dose (0 if not used)	 -
3rd day venous pressure	
(Value in the third morning after admission, in mmHg,	 -



Quality of waveform	 Good (Clear atrial or respiratory pressure oscillations)
(Interpret the visual quality of waveform)	 Moderate (Less clear pressure oscillations but a stable measurement with an appropriate modified-Valsalva response) Poor (No oscillations, increasing, no appropriate modified-Valsalva response or nonphysiological readings)
Discharged today (or follow-up is terminated for another reason) ?	○ Yes ○ No
(If "Yes" these values will be accepted as pre-discharge measurements.)	



In-hospital Course (4th day)

4th day fluid intake	
(From previous to this day morning, in mL , e.g.; 1250)	
4th day urine output	
(From previous to this day morning, in mL , e.g.; 1250. Do not add extra losses, such as paracentesis or thoracentesis)	
BUN after 4th day	
(Fourth morning value after admission, in mg/dL , e.g.; 25)	
Creatinine after 4th day	
(Fourth morning value after admission, in mg/dL , e.g.; 1.5)	
Sodium after 4th day	
(Fourth morning value after admission, in mEq/L , e.g.; 135)	
Potassium after 4th day	
(Fourth morning value after admission, in mEq/L , e.g.; 4.5)	 -
Total intravenous furosemide equivalent of loop	
diuretic dose (40 mg furosemide po=20 mg furosemide iv=20 mg torasemide po)	
Total asetozolamide dose (0 if not used)	
Total thiazide dose (0 if not used)	
Total MRA dose (0 if not used)	
4th day venous pressure	
(Value in the fourth morning after admission, in mmHg,	

e.g..; 25)



Quality of waveform	 Good (Clear atrial or respiratory pressure oscillations)
(Interpret the visual quality of waveform)	 Moderate (Less clear pressure oscillations but a stable measurement with an appropriate modified-Valsalva response) Poor (No oscillations, increasing, no appropriate modified-Valsalva response or nonphysiological readings)
Discharged today (or follow-up is terminated for another reason) ?	○ Yes ○ No
(If "Yes" these values will be accepted as pre-discharge measurements.)	



In-hospital Course (5th day)

5th day fluid intake	
(From previous to this day morning, in mL , e.g.; 1250)	
5th day urine output	
(From previous to this day morning, in mL , e.g.; 1250. Do not add extra losses, such as paracentesis or thoracentesis)	
BUN after 5th day	
(Fifth morning value after admission, in mg/dL , e.g.; 25)	
Creatinine after 5th day	
(Fifth morning value after admission, in mg/dL , e.g.; 1.5)	
Sodium after 5th day	
(Fifth morning value after admission, in mEq/L , e.g.; 135)	
Potassium after 5th day	
(Fifth morning value after admission, in mEq/L , e.g.; 4.5)	
Total intravenous furosemide equivalent of loop diuretic dose	
(40 mg furosemide po=20 mg furosemide iv=20 mg torasemide po)	
Total asetozolamide dose (0 if not used)	
Total thiazide dose (0 if not used)	
Total MRA dose (0 if not used)	
5th day venous pressure	
(Value in the fifth morning after admission, in mmHg,	



Quality of waveform	 Good (Clear atrial or respiratory pressure oscillations)
(Interpret the visual quality of waveform)	 Moderate (Less clear pressure oscillations but a stable measurement with an appropriate modified-Valsalva response) Poor (No oscillations, increasing, no appropriate modified-Valsalva response or nonphysiological readings)
Discharged today (or follow-up is terminated for another reason) ?	○ Yes ○ No
(If "Yes" these values will be accepted as pre-discharge measurements.)	



In-hospital Course (6th day)

6th day fluid intake	
(From previous to this day morning, in mL , e.g.; 1250)	
6th day urine output	
(From previous to this day morning, in mL , e.g.; 1250. Do not add extra losses, such as paracentesis or thoracentesis)	
BUN after 6th day	
(Sixth morning value after admission, in mg/dL , e.g.; 25)	
Creatinine after 6th day	
(Sixth morning value after admission, in mg/dL , e.g.; 1.5)	
Sodium after 6th day	
(Sixth morning value after admission, in mEq/L , e.g.; 135)	
Potassium after 6th day	
(Sixth morning value after admission, in mEq/L , e.g.; 4.5)	
Total intravenous furosemide equivalent of loop diuretic dose	
(40 mg furosemide po=20 mg furosemide iv=20 mg torasemide po)	
Total asetozolamide dose (0 if not used)	
Total thiazide dose (0 if not used)	
Total MRA dose (0 if not used)	
6th day venous pressure	
(Value in the sixth morning after admission, in mmHg, e.g; 25)	



Quality of waveform	 Good (Clear atrial or respiratory pressure oscillations)
(Interpret the visual quality of waveform)	 Moderate (Less clear pressure oscillations but a stable measurement with an appropriate modified-Valsalva response) Poor (No oscillations, increasing, no appropriate modified-Valsalva response or nonphysiological readings)
Discharged today (or follow-up is terminated for another reason) ?	○ Yes ○ No
(If "Yes" these values will be accepted as pre-discharge measurements.)	



In-hospital Course (7th day)

7th day fluid intake	
(From previous to this day morning, in mL , e.g.; 1250)	
7th day urine output	
(From previous to this day morning, in mL , e.g.; 1250. Do not add extra losses, such as paracentesis or thoracentesis)	
BUN after 7th day	
(Seventh morning value after admission, in mg/dL , e.g.; 25)	
Creatinine after 7th day	
(Seventh morning value after admission, in mg/dL , e.g.; 1.5)	
Sodium after 7th day	
(Seventh morning value after admission, in mEq/L , e.g.; 135)	
Potassium after 7th day	
(Seventh morning value after admission, in mEq/L , e.g.; 4.5)	
Total intravenous furosemide equivalent of loop diuretic dose	
(40 mg furosemide po=20 mg furosemide iv=20 mg torasemide po)	
Total asetozolamide dose (0 if not used)	
Total thiazide dose (0 if not used)	
Total MRA dose (0 if not used)	
7th day venous pressure	
(Value in the seventh morning after admission, in mmHg, e.g; 25)	



Quality of waveform	 Good (Clear atrial or respiratory pressure oscillations)
(Interpret the visual quality of waveform)	 Moderate (Less clear pressure oscillations but a stable measurement with an appropriate modified-Valsalva response) Poor (No oscillations, increasing, no appropriate modified-Valsalva response or nonphysiological readings)
Discharged today (or follow-up is terminated for another reason) ?	○ Yes ○ No
(If "Yes" these values will be accepted as pre-discharge measurements.)	



In-hospital Adverse Events

Technical problems in pressure monitorization	⊖ Yes	⊖ No
(Unable to measure venous pressure on admission, before pre-discharge or on three consecutive days)		
*Criterion for exclusion from long-term follow-up (If admission and predischarge pressures cannot be measured) !		
Symptomatic hypotension requiring intervention	⊖ Yes	⊖ No
(Systolic blood pressure < 90 mmHg requiring fluid resuscitation or vasopressor use.)		
Any need for high dose inotropes or mechanical support (intraaortic balloon etc.)	⊖ Yes	⊖ No
(>10 mcg/kg/min dopamine or dobutamine, any dose of noradrenaline or adrenaline. Milrinon or levosimendan can be ignored.)		
*Criterion for exclusion from long-term follow-up !		
The development of clinical thrombophylebitis	⊖ Yes	⊖ No
(Redness, warmness or tenderness on any previously used vein)		
Any need for veno-venous hemofiltration or dialysis	⊖ Yes	⊖ No
(Any unplanned need for veno-venous hemofiltration or dialysis during hospitalization.)		
*Criterion for exclusion from long-term follow-up !		
In-hospital intubation	⊖ Yes	⊖ No
*Criterion for exclusion from long-term follow-up !		
In-hospital cardiopulmonary resuscitation	⊖ Yes	⊖ No
*Criterion for exclusion from long-term follow-up !		
Exclusion date		
In-hospital mortality	⊖ Yes	⊖ No
*Criterion for exclusion from long-term follow-up !		
Mortality date		



Predischarge Findings

As an in-hospital safety endpoint has occured, this patient has been excluded from long-term follow-up. You do not need to fill any measurement on this page.

(If this has not occured and you think this is a mistake, please check the form entitled "In-hospital adverse events".)

Dischareg date
(Select as day, month and year.)
Subjective dyspnea score
 None Rare Frequent Always
Subjective orthopnea score
 None Rare Frequent Always
Subjective fatigue score
 None Rare Frequent Always
Pretibial edema
 ○ None ○ 1+ ○ 2+ ○ 3+ ○ 4+
Pulmonary rales
 None Limited to the bases Lower half More than lower half
Jugular venous distention
(Compared to angle of Louis while lying at 45 degree supine position.)
 Unobservable Normal (< 4.5 cm) High (>4.5 cm) but pulsations can be seen Exceeds angulus mandibula
BUN on discharge

(Just before discharge, in mg/dL, e.g.; 12)



Creatinine on discharge (Just before discharge, in mg/dL, e.g.; 1.2)	
Sodium on discharge (Just before or after admission, in mEq/L, e.g.; 142)	
Potassium on discharge (Just before discharge, in mEq/L, e.g.; 4.2)	
Hemoglobin on discharge (Just before discharge, in g/dL, e.g.; 12.3)	
Hematocrit on discharge (Just before discharge, in %, e.g.; 31)	
Albumin on discharge (Just before discharge, in g/dL, e.g.; 3.1)	
Total protein on discharge (Just before discharge, in g/dL, e.g.; 5.2)	
BNP/NT-proPNP on discharge (Just before discharge, in pg/mL, e.g.; 125)	
Uric acid on discharge (Just before discharge, in mg/dL, e.g.; 5.5)	
Weight (Just before discharge, in kilograms)	
Additions to total negative balance (Additional fluid losses, such as paracentesis, thoracentesis, in mL. E.g., 1.200. If absent, enter 0.)	
Venous pressure	
(in mmHg; e.g., 5. If the subject is in standard therapy arm, caregiver should be blinded to this measurement.)	
Quality of waveform	 Good (Clear atrial or respiratory pressure oscillations)

(Interpret the visual quality of waveform)

- oscillations)
- Moderate (Less clear pressure oscillations but a stable measurement with an appropriate modified-Valsalva response)
 Poor (No oscillations, increasing, no appropriate modified-Valsalva response or nonphysiological readings)
- readings)



Treatment on Discarge

As an in-hospital safety endpoint has occured, this patient has been excluded from long-term follow-up. You do not need to fill any measurement on this page.

(If this has not occured and you think this is a mistake, please check the form entitled "In-hospital adverse events".)

Aspirin (Prescribed medications at discharge)	⊖ Yes	⊖ No
P2Y12 inhibitor (Prescribed medications at discharge)	⊖ Yes	⊖ No
OAC/NOAC (Prescribed medications at discharge)	⊖ Yes	⊖ No
Beta-blocker (Prescribed medications at discharge)	⊖ Yes	⊖ No
ACEi/ARB (Prescribed medications at discharge)	⊖ Yes	⊖ No
ARNI (Prescribed medications at discharge)	⊖ Yes	⊖ No
SGLT2i (Prescribed medications at discharge)	⊖ Yes	⊖ No
MRA (Prescribed medications at discharge)	⊖ Yes	⊖ No
Loop diuretic (Prescribed medications at discharge)	⊖ Yes	⊖ No
Oral furosemide equivalent loop diuretic dose (40 mg furosemide po=20 mg furosemide iv=20 mg torasemide po)		
Digoxin (Prescribed medications at discharge)	⊖ Yes	⊖ No
Statin (Prescribed medications at discharge)	⊖ Yes	⊖ No



Long-term Follow-up

As an in-hospital safety endpoint has occured, this patient has been excluded from long-term follow-up. You do not need to fill any measurement on this page.

(If this has not occured and you think this is a mistake, please check the form entitled "In-hospital adverse events".)

Long-term mortality (Death in the first year)	⊖ Yes	⊖ No	🔿 Unknown
Mortality date			
All-cause long-term hospitalization (Emergency department visit or hospital admission due to any cause in the first year)	⊖ Yes	⊖ No	🔿 Unkonwn
Date of all-cause hospitalization (The first date of emergency department visit or hospital admission due to any cause in the first year)			
Long-term hospitalization due to HF (Emergency department visit or hospital admission due to HF in the first year)	⊖ Yes	⊖ No	🔿 Unknown
Date of HF-related hospitalization (The first date of emergency department visit or hospital admission due to HF in the first year)			