

8/3/24, 9:40

Evaluation of Dynamic Arterial Elastance Efficacy and Safety during Vasopressor Support Weaning in Septic Shock Patients: A Random...

Evaluation of Dynamic Arterial Elastance Efficacy and Safety during Vasopressor Support Weaning in Septic Shock Patients: A Randomized Controlled Trial Protocol: Case report form

Fundación Santa Fe de Bogotá, Department of Critical Medicine and Intensive Care

1. Identification of the patient in the study

2. Group assigned by randomization

Mark only one oval.

☐ EaDyn (intervention)

☐ MAP (control)

3. Inclusion criteria (check all those applying)

Check all that apply.

☐ Patient over 18 years old

☐ Septic shock patients defined according to the third international consensus of sepsis as patients who clinically present vasopressor support requirement to maintain a MAP \geq 65 mmHg or a lactate level \geq 2 mmol/L in the absence of hypovolemia

☐ SOFA score of \geq 4 points

☐ Patients requiring vasopressor support for a period of 4 hours or more

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4. Exclusion criteria (check all applicable)

Check all that apply.

- ☐ Pregnant women
- ☐ Hemodynamically unstable cardiac arrhythmias
- ☐ Treatment with another vasopressor other than noradrenaline or inotropic support requirement
- ☐ Patients with right heart failure
- ☐ Patients diagnosed with cirrhosis of the liver
- ☐ Patients who have received renal and/or hepatic transplantation
- ☐ Patients with a high probability of mortality in 24 hours defined according to medical criteria

5. Age (years)

6. Weight (Kg)

7. Diagnosis according to ICD-10

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8. Intensive inpatient care unit*Mark only one oval.*

- ☐ Surgical unit
- ☐ Neurological unit
- ☐ Sepsis / respiratory unit
- ☐ Cardiovascular
- ☐ Burn unit

9. SOFA score at start of vasopressor support

10. Dose of noradrenaline at study inclusion (mcg/kg/min)

11. Total, noradrenaline infusion duration (hours)

12. Total, of noradrenaline administered (mg)

13. Total, of liquids administered (mL/kg/h)

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14. Hypotension during weaning (MAP < 50 mmHg)*Mark only one oval.*☐ Yes☐ No**15. Death***Mark only one oval.*☐ Yes☐ No**16. Stay in ICU (time when the patient is without vasopressor and ventilatory support, days)**

17. Stay in hospital (time at which doctor gives the order in the medical history of discharge, days)

Variables to be taken daily*DAY 1***18. Duration of NE (h)**

19. Dose of NE (mg)

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20.

Administered liquids (mL)

21.

Diuresis (mL)

22.

Balance of liquids (mL)

23.

Blood products

Variables to be taken daily

DAY 2

24.

Duration of NE (h)

25.

Dose of NE (mg)

26.

Administered liquids (mL)

27.

Diuresis (mL)

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28.

Balance of liquids (mL)

29.

Blood products

Variables to be taken daily

DAY 3

30.

Duration of NE (h)

31.

Dose of NE (mg)

32.

Administered liquids (mL)

33.

Diuresis (mL)

34.

Balance of liquids (mL)

35.

Blood products

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Variables to be taken daily

DAY 4

36. Duration of NE (h)

37. Dose of NE (mg)

38. Administered liquids (mL)

39. Diuresis (mL)

40. Balance of liquids (mL)

41. Blood products

Variables to be taken daily

DAY 5

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42. **Duration of NE (h)**

43. **Dose of NE (mg)**

44. **Administered liquids (mL)**

45. **Diuresis (mL)**

46. **Balance of liquids (mL)**

47. **Blood products**

Variables to be taken daily

DAY 6

48. **Duration of NE (h)**

49. **Dose of NE (mg)**

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50.

Administered liquids (mL)

51.

Diuresis (mL)

52.

Balance of liquids (mL)

53.

Blood products

Variables to be taken daily

DAY 7

54.

Duration of NE (h)

55.

Dose of NE (mg)

56.

Administered liquids (mL)

57.

Diuresis (mL)

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58. **Balance of liquids (mL)**

59. **Blood products**

Variables to be taken daily

DAY 8

60. **Duration of NE (h)**

61. **Dose of NE (mg)**

62. **Administered liquids (mL)**

63. **Diuresis (mL)**

64. **Balance of liquids (mL)**

65. **Blood products**

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Variables to be taken daily

DAY 9

66. **Duration of NE (h)**

67. **Dose of NE (mg)**

68. **Administered liquids (mL)**

69. **Diuresis (mL)**

70. **Balance of liquids (mL)**

71. **Blood products**

Variables to be taken daily

DAY 10

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72. **Duration of NE (h)**

73. **Dose of NE (mg)**

74. **Administered liquids (mL)**

75. **Diuresis (mL)**

76. **Balance of liquids (mL)**

77. **Blood products***Mark only one oval.*☐ Yes☐ No***Variables that change in the three points of measurment****At the beginning of administration of Noradrenaline*78. **SOFA score**

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79. **Heart rate**

80. **MAP**

81. **Central venous pressure**

82. **Cardiac index (CI)**

83. **Saline solution administered (mL)**

84. **Albumin (mL)**

85. **Blood products***Mark only one oval.*☐ Yes☐ No86. **Albumin (mL)**

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87.

Dose of noradrenaline (mg)

88.

Lactate (mmol/L)

89.

Venous saturation

90.

Diuresis (mL)

Variables that change in the three points of measurment

At the beginning of the weaning of vasopressor support

91.

SOFA score

92.

Heart rate

93.

MAP

94.

Central venous pressure

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95. **Cardiac index (CI)**

96. **Saline solution administered (mL)**

97. **Albumin (mL)**

98. **Blood products***Mark only one oval.*☐ Yes☐ No99. **Albumin (mL)**

100. **Dose of noradrenaline (mg)**

101. **Lactate (mmol/L)**

102. **Venous saturation**

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103.

Diuresis (mL)

Variables that change in the three points of measurment

At the end of weaning vasopressor support

104.

SOFA score

105.

Heart rate

106.

MAP

107.

Central venous pressure

108.

Cardiac index (CI)

109.

Saline solution administered (mL)

110.

Albumin (mL)

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111. **Blood products**

Mark only one oval.

- ☐ Yes
- ☐ No

112. **Albumin (mL)**

113. **Dose of noradrenaline (mg)**

114. **Lactate (mmol/L)**

115. **Venous saturation**

116. **Diuresis (mL)**

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