

prob.label

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|_|_| / |_|_|

patNo. / initials principal investigator

Impact of carbohydrate reduced nutrition in septic patients on ICU - a prospective randomized controlled trial

201_|_|_|_|_|.

Inclusion criteria	Yes	No
• age \geq 18 years	<input type="checkbox"/>	<input type="checkbox"/>
• Diagnosis of sepsis according to current Sepsis-3 definition: <ol style="list-style-type: none"> 1. Suspected or proven infection 2. Organ dysfunction: increase of SOFA-score \geq 2scoring points 	<input type="checkbox"/>	<input type="checkbox"/>
• Inclusion during 36h after diagnosis of sepsis		
• Mechanical ventilation <72h		
• Written informed consent or positive vote of an independent consultant	<input type="checkbox"/>	<input type="checkbox"/>

Exclusion criteria	Yes	No
• Refusal of the patient or lack of consent	<input type="checkbox"/>	<input type="checkbox"/>
• Lack of medical indication and/or contraindications to administration of enteral nutrition	<input type="checkbox"/>	<input type="checkbox"/>
• Age < 18 years	<input type="checkbox"/>	<input type="checkbox"/>
• Anaemia (Hb < 8,0g/dl)	<input type="checkbox"/>	<input type="checkbox"/>
• Relationship to the principal investigator (relatives, friends)	<input type="checkbox"/>	<input type="checkbox"/>
• Pre-existing conditions <ul style="list-style-type: none"> ○ Insulin depended diabetes mellitus type I and II ○ Other severe metabolic disorders or autoimmune disorders ○ Known moderate to severe liver insufficiency or dysfunction ○ Patients with severe refractory metabolic acidosis 	<input type="checkbox"/>	<input type="checkbox"/>
• Do not resuscitate order	<input type="checkbox"/>	<input type="checkbox"/>
• Pregnancy or lactation period	<input type="checkbox"/>	<input type="checkbox"/>

- Copy patient documents! (medical history, comorbidity, long term medication, physical examination, ECG, vital signs, etc.) ☐ done
- ☐ male ☐ female height |_|_|_| cm weight |_|_|_|_| kg BMI |_|_|_| kg/m²
- blood pressure |_|_|_| / |_|_| cardiac frequency |_|_|_| /min temperature |_|_|_| °C
- Pregnancy impossible ☐, if possible => see next line

Pregnancy test (urine) **result:** ☐ neg. ☐ pos. → exclusion
- Note participation in the study in medical record (i.e. PDMS)! ☐ done

03.06.2019

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● **Studies related documentation**

- Medical history (space for description):

- Allergies:

- Surgeries during the last 5 years:

- Infective diseases during the last 12 months: YES ☐ / No ☐

- ICU parameters:

SOFA score (ascertained until day 14 or until release of ICU)

Day 1 _____	day 2 _____	day 3 _____
day 4 _____	day 5 _____	day 6 _____
day 7 _____	day 8 _____	day 9 _____
day 10 _____	day 11 _____	day 12 _____
day 13 _____	day 14 _____	

- Vasopressor therapy (yes/no, ascertained until day 14 or until release of ICU)

day 1 _____	day 2 _____	day 3 _____
day 4 _____	day 5 _____	day 6 _____
day 7 _____	day 8 _____	day 9 _____
day 10 _____	day 11 _____	day 12 _____
day 13 _____	day 14 _____	

- Mechanical ventilation (ascertained until day 14 or until release of ICU)

day 1 _____	day 2 _____	day 3 _____
day 4 _____	day 5 _____	day 6 _____
day 7 _____	day 8 _____	day 9 _____
day 10 _____	day 11 _____	day 12 _____
day 13 _____	day 14 _____	

date 201__|_|_|_|_|_|_|_|

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▪ KDIGO-Score (ascertained until day 14 or until release of ICU)

day 1 _____	day 2 _____	day 3 _____
day 4 _____	day 5 _____	day 6 _____
day 7 _____	day 8 _____	day 9 _____
day 10 _____	day 11 _____	day 12 _____
day 13 _____	day 14 _____	

▪ Immunosuppression (yes/no, ascertained until day 14 or until release of ICU)

day 1 _____	day 2 _____	day 3 _____
day 4 _____	day 5 _____	day 6 _____
day 7 _____	day 8 _____	day 9 _____
day 10 _____	day 11 _____	day 12 _____
day 13 _____	day 14 _____	

▪ Renal dialysis (yes/no, ascertained until day 14 or until release of ICU)

day 1 _____	day 2 _____	day 3 _____
day 4 _____	day 5 _____	day 6 _____
day 7 _____	day 8 _____	day 9 _____
day 10 _____	day 11 _____	day 12 _____
day 13 _____	day 14 _____	

▪ Antibiotics therapy (yes/no, ascertained until day 14 or until release of ICU)

day 1 _____	day 2 _____	day 3 _____
day 4 _____	day 5 _____	day 6 _____
day 7 _____	day 8 _____	day 9 _____
day 10 _____	day 11 _____	day 12 _____
day 13 _____	day 14 _____	

date 201__|_|_|_|_|_|_|

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▪ Secondary infections (yes/no, ascertained until day 14 or until release of ICU)

day 1 _____	day 2 _____	day 3 _____
day 4 _____	day 5 _____	day 6 _____
day 7 _____	day 8 _____	day 9 _____
day 10 _____	day 11 _____	day 12 _____
day 13 _____	day 14 _____	

▪ Daily print out of routine laboratory investigations (* incl. CMV+EBV-PCR)

day 1 _____	day 2 _____	day 3 _____
day 4 _____	day 5 _____	day 6 _____
day 7* _____	day 8 _____	day 9 _____
day 10 _____	day 11 _____	day 12 _____
day 13 _____	day 14* _____	

▪ Daily print out of the vital signs' trend

day 1 _____	day 2 _____	day 3 _____
day 4 _____	day 5 _____	day 6 _____
day 7 _____	day 8 _____	day 9 _____
day 10 _____	day 11 _____	day 12 _____
day 13 _____	day 14 _____	

▪ Study-related blood sampling

day 1 _____	day 14 _____
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date 201__|_|_|_|_|_|

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