

SCREENING			Name	
Subject ID	001	(fill out with 4 additional digits e.g. 0010001)	Date of Birth	
			Orbis ID	
Investigator			Signature	
Age [years]			Gender	male/female
Height [cm]			Weight [kg]	
Admission type*			Type of surgery#	
Date of hospital admission			Date of surgery	
Date of ICU admission			Date of screening	YES/NO
MV since		:	PSV hours:	YES/NO
Inclusion criteria				
Age ≥ 18 years			YES/NO	
Duration of controlled mechanical ventilation >24h			YES/NO	
Availability of Dräger Infinity 500 ventilator (ready to use)			YES/NO	
Informed consent according to local regulations			YES/NO	
Temperature ≤ 39 °C			YES/NO	
Hemoglobin ≥ 6 g/dl (3,72mmol/l)			YES/NO	
PaO ₂ /FiO ₂ ≥ 150 mmHg with PEEP ≤ 16 cmH ₂ O			YES/NO	
Ability to breathe spontaneously			YES/NO	
Exclusion criteria				
Participation in another interventional trial within the last four weeks before enrolment in this trial			YES/NO	
Peripheral neurological disease associated with impairment of the respiratory pump			YES/NO	
Muscular disease associated with impairment of the respiratory pump			YES/NO	
Unstable thorax with paradoxical chest wall movement			YES/NO	
Planned surgery within 72 hours under general anaesthesia			YES/NO	
Difficult airway/intubation			YES/NO	
Existing tracheotomy at ICU admission			YES/NO	
Expected survival < 72 hours			YES/NO	
Home mechanical ventilation or on chronic oxygen therapy			YES/NO	
Suspected pregnancy			YES/NO	
Apache Score II Score				
T [°C]		PaO ₂ [kPa]		HKT
MAP [mmHg]		PaCO ₂ [kPa]		WBC [total/μL]
HR [bpm]		pH		GCS- eye
RR [bpm]		Na [mmol/L]		GCS-verbal
FiO ₂ [%]		K [mmol/L]		GCS-motor
		Crea [μmol/L]		
SOFA Score				
P/F-ratio [mmHg]		MAP [mmHg]		Dobutrex [γ]
PLT [total/μL]		Crea [μmol/L]		Arterenol [γ]
Bili [μmol/L]		GCS		Adrenalin [γ]
Chronic conditions?				
Heart	YES/NO	Respiratory	YES/NO	Renal
				YES/NO

Pre-Inclusion Test (PIT)						
Subject ID	001 _____					
Investigator						
Signature						
	Before PIT	After PIT	Before PIT	After PIT	Before PIT	After PIT
Date						
Time						
Mode**						
MV [L/min]						
RR [bpm]						
Ppeak [cmH ₂ O]						
Pmean [cmH ₂ O]						
PSV level [cmH ₂ O]						
Variability level [%]						
PEEP [cmH ₂ O]						
FiO ₂						
PaO ₂ [kPa]						
PaCO ₂ [kPa]						
pH						
T ≤ 39 °C		YES/NO	-	YES/NO	-	YES/NO
P/F Ratio ≥ 150 mmHg		YES/NO	-	YES/NO	-	YES/NO
PEEP ≤ 16 cmH ₂ O		YES/NO	-	YES/NO	-	YES/NO
pH ≥ 7.30		YES/NO	-	YES/NO	-	YES/NO
RR ≤ 40/min		YES/NO	-	YES/NO	-	YES/NO
HR 40-130/min		YES/NO	-	YES/NO	-	YES/NO
SAP 80-160 mmHg		YES/NO	-	YES/NO	-	YES/NO
Max. 0.1 µg nora, and/or adrenalin, 2 µg dopamine and/or dobutamine		YES/NO		YES/NO		YES/NO
No arrhythmias?		YES/NO		YES/NO		YES/NO
PIT passed?		YES/NO		YES/NO		YES/NO
Randomization		YES/NO		Result:	<input type="checkbox"/> conventional PSV	
					<input type="checkbox"/> noisy PSV	

Perform the PREINCLUSION TEST

Ventilate the patient for 1 hour in PSV Mode according to the following settings:

- targeted mean VT = 6-8 ml/kg
- Pressure support variability = 0%
- Maximal peak pressure = 40 cmH₂O
- Flow trigger = 2 l/min
- Inspiratory cycling-off = 25% of peak flow
- PEEP and FIO₂ for SaO₂ ≥ 92%, whereby PEEP ≥ 5 cmH₂O

If the patient shows signs of hemodynamic or respiratory distress (see next page), the test will be stopped ahead of time. If the patient fails the pre-inclusion test, mechanical ventilation is conducted according to local clinical practice. The pre-inclusion test is repeated as early as possible at discretion of the treating physician.

RANDOMIZATION at: <https://macro.medizin.tu-dresden.de>

Daily Visit					
Subject-ID	001 _____				
<input type="checkbox"/> conventional PSV			<input type="checkbox"/> noisy PSV		
Investigator					
Signature					
Variable	Day 1 <input type="checkbox"/>	Day 2 <input type="checkbox"/>	Day 3 <input type="checkbox"/>	Day 4 <input type="checkbox"/>	Day 5 <input type="checkbox"/>
Date					
Time					
Mechanical ventilation					
Mode**					
MV [L/min]					
RR [bpm]					
Ppeak [cmH ₂ O]					
Pmean [cmH ₂ O]					
PSV level [cmH ₂ O]					
Variability level [%]					
PEEP [cmH ₂ O]					
P0.1 [mbar]					
FiO ₂					
PaO ₂ [kPa]					
PaCO ₂ [kPa]					
pH					
PSV changes [No]					
PEEP changes [No]					
FiO ₂ changes [No]					
PCV/BIPAP hours [hr]					
Hemodynamics					
HR [bpm]					
MAP [mmHg]					
T [°C]					
Fluids					
Fluid balance [ml]					
Crystalloid [ml]					
Colloid [ml]					
Blood products [ml]					
Other fluids [ml]					
SOFA Score					
P/F-ratio [mmHg]					
PLT [total/μL]					
Bili [μmol/L]					
Crea [μmol/L]					
MAP [mmHg]					
GCS eye					
GCS verbal					
GCS motor					
Arterenol [$>0,1 \mu\text{g/kg/min}$]					
Adrenalin [$>0,1 \mu\text{g/kg/min}$]					
Dobutamin [$>0,1 \mu\text{g/kg/min}$]					
AE/SAE					
Comments					

Daily Visit					
Subject-ID	001 _____				
Medication	Day 1	Day 2	Day 3	Day 4	Day 5
Sedatives? [total mg]					
Analgetics? [total mg]					
NMBAs? [total mg]					
Corticosteroids? [total mg]					
Catecholamines? [total mg]					
Extubation criteria					
RASS \geq -3	YES/NO	YES/NO	YES/NO	YES/NO	YES/NO
RASS Score					
BPS \leq 5	YES/NO	YES/NO	YES/NO	YES/NO	YES/NO
BPS - facial expression					
BPS - upper limbs					
BPS - compliance with MV					
Raise hands vs gravity	YES/NO	YES/NO	YES/NO	YES/NO	YES/NO
T 36-39°C	YES/NO	YES/NO	YES/NO	YES/NO	YES/NO
Coughing after deflation	YES/NO	YES/NO	YES/NO	YES/NO	YES/NO
RR 8-30/min	YES/NO	YES/NO	YES/NO	YES/NO	YES/NO
PaO ₂ /FiO ₂ \geq 200mmHg (\geq 150mmHG if COPD)	YES/NO	YES/NO	YES/NO	YES/NO	YES/NO
PSV Level \leq 8cmH ₂ O	YES/NO	YES/NO	YES/NO	YES/NO	YES/NO
PEEP \leq 8cmH ₂ O	YES/NO	YES/NO	YES/NO	YES/NO	YES/NO
SAP 90-160mmHg	YES/NO	YES/NO	YES/NO	YES/NO	YES/NO
HR 40-130/min	YES/NO	YES/NO	YES/NO	YES/NO	YES/NO
No arrhythmias?	YES/NO	YES/NO	YES/NO	YES/NO	YES/NO
Time all criteria fulfilled [hh:mm]					
Extubation	YES/NO	YES/NO	YES/NO	YES/NO	YES/NO
Time of extubation [hh:mm]					
Successfull >72h ?	YES/NO	YES/NO	YES/NO	YES/NO	YES/NO
Date [dd.mm.yy] / Time [hh:mm]					

Extubation				
Subject ID		001 _____		
Investigator				
Signature				
Ventilator settings at time of extubation				
Date				
Time				
Mode**				
MV [L/min]				
RR [bpm]				
Ppeak [cmH ₂ O]				
Pmean [cmH ₂ O]				
PSV level [cmH ₂ O]				
Variability level [%]				
PEEP [cmH ₂ O]				
P0.1 [mbar]				
FiO ₂				
PaO ₂ [kPa]				
PaCO ₂ [kPa]				
pH				
PSV changes [No]				
PEEP changes [No]				
FiO ₂ changes [No]				
PCV/BIPAP hours [hr]				
ICDSC Score				
<i>Altered level of consciousness [A to E]</i>				
<i>Inattentiveness</i>	[yes/no]		[yes/no]	[yes/no]
<i>Disorientation</i>	[yes/no]		[yes/no]	[yes/no]
<i>Hallucination - delusion – psychosis</i>	[yes/no]		[yes/no]	[yes/no]
<i>Psychomotor agitation or retardation</i>	[yes/no]		[yes/no]	[yes/no]
<i>Inappropriate speech or mood</i>	[yes/no]		[yes/no]	[yes/no]
<i>Sleep/wake cycle disturbance</i>	[yes/no]		[yes/no]	[yes/no]
<i>Symptom fluctuation</i>	[yes/no]		[yes/no]	[yes/no]
[no assessment/0-8 points]				
Sucessfull >72h ?	YES/NO		YES/NO	YES/NO
Date [dd.mm.yy] / Time [hh:mm]				
NIV & Complications				
NIV after extubation	YES/NO			
Maximum CPAP Level [cmH ₂ O]				
NIV with PSV	YES/NO			
Maximum PSV level [cmH ₂ O]				
Total No of NIV hrs [hours]				
No. of NIV days after succ. Extubation [days]				
Tracheostomy since randomization	YES/NO		Date	
Self-extubation since randomization	YES/NO		Date	

Discharge			
Subject ID	001 _____		
Investigator	Signature		
	ICU Discharge	Hospital Discharge	
Date			
	Discharge Destination [Home/Other Hospital/Care/Death]		
ADVERSE EVENTS			
Subject ID	001 _____		
Investigator	Signature		
Description of event			
Comments			
Serious AE	YES/NO		
Start Date / Time			
End Date / Time		Continuing at study end?	YES/NO
Initial intensity	mild / moderate / severe / n.a.		
Study therapy	continued / discontinued		
Treatment?	YES/NO		
Most extreme intensity	mild / moderate / severe / n.a.		
Relationship to study therapy	unrelated / remote / possible / probable / n.a.		
Outcome	resolved-no sequelae / resolved-sequelae / unresolved / death / unknown		
	Specify treatment:		

Short Appendix:

Behavioural Pain Scale:

Item	Description	Score
Facial expression	Relaxed	1
	Partially tightened (e.g., brow lowering)	2
	Fully tightened (e.g., eyelid closing)	3
	Grimacing	4
Upper limbs	No movement	1
	Partially bent	2
	Fully bent with finger flexion	3
	Permanently retracted	4
Compliance with ventilation	Tolerating movement	1
	Coughing but tolerating ventilation for most of the time	2
	Fighting ventilator	3
	Unable to control ventilation	4

[Kg]	µg/kg/min	mg/h
50	0,1	0,30
60	0,1	0,36
70	0,1	0,42
80	0,1	0,48
90	0,1	0,54
100	0,1	0,60

Conversion catecholamines
µg/kg/h <-> mg/h

Richmond Agitation Sedation Scale (RASS)

- +4 – Overtly combative, violent, immediate danger to staff**
- +3 – Pulls or removes tube(s) or catheter(s); aggressive**
- +2 – Frequent nonpurposeful movement, fights ventilator**
- +1 – Anxious but movements not aggressive or vigorous**
- 0 – Alert and calm**
- 1 – Not fully alert, but has sustained awakening (eye-opening or eye-contact) in response to voice (>10 seconds)**
- 2 – Briefly awakens with eye contact to voice (<10 seconds)**
- 3 – Movement or eye opening to voice, but no eye contact**
- 4 – No response to voice, but movement or eye opening to physical stimulation**
- 5 – No response to voice or physical stimulation**

Type of surgery:

- 1 = General Surgery/Plastic
- 2 = Orthopaedic
- 3 = Neurosurgery
- 4 = Gynecology
- 5 = Oto-rhino-laryngology/Oral-maxillofacial
- 6 = Urology
- 7 = Other

*Admission type:

- 1 = Postsurgical following elective surgery
- 2 = Postsurgical following emergency surgery
- 3 = Presurgical, emergency
- 4 = Presurgical, elective
- 5 = Non surgery

C. Chronic Health Points

Has the patient a known history (diagnosed before ICU admission) of organ system insufficiency or compromised immune system?

CARDIOVASCULAR: Yes No

NYHA IV

RESPIRATORY: Yes No

chron. restrictive disease, chron obstructive disease or vascular disease resulting in severe exercise restriction i.e. unable to climb stairs or perform household duties;
documented chronic hypoxia
documented hypercapnia,
documented secondary polycythemia
severe pulmonary hypertension (>40mmHg)
respirator dependency

RENAL: Yes No

receiving chronic dialysis

ICDSC Score

The Intensive Care Delirium Screening Checklist

Checklist Item	Description
Altered level of consciousness ^a	
A	No response
B	Response to intense and repeated stimulation
C	Response to mild or moderate stimulation
D	Normal wakefulness
E	Exaggerated response to normal stimulation
Inattentiveness	Difficulty following instructions or easily distracted
Disorientation	To time, place, or person
Hallucination-delusion-psychosis	Clinical manifestation or suggestive behavior
Psychomotor agitation or retardation	Agitation requiring use of drugs or restraints, or slowing
Inappropriate speech or mood	Related to events or situation, or incoherent speech
Sleep/wake cycle disturbance	Sleeping <4 hours/day, waking at night, sleeping all day
Symptom fluctuation	Symptoms above occurring intermittently
Total score	0 to 8

^aIf A or B, then no other items are assessed that day.

Obvious manifestation of an item = 1 point

No manifestation of an item or no assessment possible = 0 points

The score of each item is 0 or 1.

A (coma) or B (stupor) means no evaluation. No points

C or E gives 1 point, zero points for D.