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Study:

Continuous Wireless Monitoring of Vital Signs and Automated Alerts of Postsurgical Patient Deterioration.

NCT04640415

Statistical analysis plan

Version 1

Primary Outcome Measure:

Cumulative duration

Cumulative duration of one or more deviations in vital signs. List of vital signs, and normal limits detailed in protocol, whichever comes first.

Vital signs value deviations are calculated per 24 hours of monitoring time.

[Time Frame: First 5 days from randomization or until discharge]

Secondary Outcome Measures:

- *Frequency of sustained deviation alerts*
  Frequency of each of the sustained deviations in vital signs. List of vital signs, and normal limits detailed in protocol.
  Number of alarms are calculated as the number of alarms per 24 hours.
  [Time Frame: First 5 days from randomization or until discharge, whichever comes first]
- *AE during the first 7 days and the first 30 days*
- *SAE during the first 7 days and the first 30 days*

Tertiary Outcome Measures:

1. *Length of hospital stay*
   Length of hospital stay
   [Time Frame: 30 days from randomization and 6 months]
2. *Patient related post-admission healthcare expenses*
   Total patient-related healthcare expenses in patients experiencing adverse clinical outcomes compared to patients without such outcomes and the effect of the study intervention on expenses
   [Time Frame: 2 years]
3. *Staff response time (intervention group only)*
   Time from the staff is notified by app, until they respond by selecting 'check on patient' in app
   Stratified according to time of day
   [Time Frame: Up to 5th postoperative day or until discharge, whichever comes first]

Outcome analysis:

- *Intention to treat analysis*
    - Patient outcomes are analyzed based on the randomization groups.
- *Per-protocol analysis*
    - Patients included in the intervention are those with:
        - intervention patients with alerts with at least one registered use of the app in relation to an alert, as indicated if the “attend”, “postpone/snooze” or “transfer” buttons have been used.
          OR
        - intervention patients with no alerts, are also included in the intervention group.

      AND
    - at least 12 hours of monitoring with valid data transfer.
    - Patients in the control-group are all patients from the control group with at least 12 hours of monitoring.

Data analysis:

- Vital values: Gaps in vital value data were not imputed.
  Durations will be calculated in minutes per 24 hours (1440 minutes) of monitoring.

- Data will be presented with descriptive statistics.
  Categorical data will be tested with Fishers exact test.
  Continuous data will be tested with Wilcoxon Mann-Whitney U test.
  Time-till-event will be tested with cox-regression.

- For statistical tests and alpha of < 0.05 will be considered statistically significant.

Table 1: Patient demographics

	Control arm N = 200	Intervention arm N = 200
Age, mean		
Male, no (%)		
ASA class		
I		
II		
III		
>IV		
Smoking status		
Never smoked		
Former smoker		
Current smoker		
Pack years for former and current smokers (mean)		
Preexisting conditions, n (%)		
COPD		
Vascular insufficiency		
Chronic arterial hypertension		
Diabetes Mellitus		
Type of surgery		
Abdominal		
Vascular		
Urologic		
Orthopedic		

Table 2: Primary outcomes - Cumulative duration of deviating vital values per 24 hours

	Intention to treat analysis		
	Control arm N = 200	Intervention arm N = 200	p-value
Total cumulative			
Respiratory			
SpO2 < 92 %			
SpO2 < 88 %			
SpO2 < 85 %			
SpO2 < 80 %			
RF < 5 min^{-1}			
RF < 11 min^{-1}			
RF > 24 min^{-1}			
RF > 30 min^{-1}			
Circulatory			
HR < 30 min^{-1}			
HR [30 - 40] min^{-1}			
HR > 110 min^{-1}			
HR > 130 min^{-1}			
SBP < 70 mmHg			
SBP < 90 mmHg			
SBP > 180 mmHg			
SBP > 220 mmHg			

Table 3: Secondary outcomes - Median number of alarms for sustained deviations per 24 hours. For control patients the number is the theoretical number of alarms a system would issue.

	Control arm N = 200	Intervention arm N = 200	p-value
Desaturation			
SpO2 < 92 % for > 60 min			
SpO2 < 88 % for > 10min			
SpO2 < 85 % for > 5 min			
SpO2 < 80 % for > 1 min			
Bradypnea			
RF < 5 min^{-1} for > 1 min			
RF < 11 min^{-1} for > 15 min			
Tachypnea			
RF > 24 min^{-1} for > 15 min			
RF > 30 min^{-1} for > 5 min			
Bradycardia			
HR < 30 min^{-1} for > 1 min			
HR [30 - 40] min^{-1} for > 5 min			
Tachycardia			
HR > 110 min^{-1} for > 60 min			
HR > 130 min^{-1} for > 30 min			
Hypotension			
SBP < 70 mmHg for > 30 min			
SBP < 90 mmHg for > 60 min			
Hypertension			
SBP > 180 mmHg for > 60 min			
SBP > 220 mmHg for > 30 min			

Table 4: Tertiary outcomes

	Intention to treat analysis		**Per protocol analysis**	
	Control arm N = 200	Intervention arm N = 200	Control arm N = 280	Intervention arm N = 120
Serious Adverse Events at 7 days / n (%)	XX (xx %)	XX (xx %)	XX (xx %)	XX (xx %)
Serious Adverse Events at 30 days / n (%)	XX (xx %)	XX (xx %)	XX (xx %)	XX (xx %)
Death / n (%)	XX (xx %)	XX (xx %)	XX (xx %)	XX (xx %)
Length of stay / days [IQR]	X [X-XX]	X [X-XX]	X [X-XX]	X [X-XX]
Reoperation / n (%)	XX (xx %)	XX (xx %)	XX (xx %)	XX (xx %)