Continuous monitoring of patients in and after the acute admission ward to optimize clinical pathways

Published: 21-07-2021
Last updated: 05-04-2024

Objective: The primary objective is to assess the effects of continuous monitoring of patients in the acute admission ward (AAW) with a wearable sensor on the percentage of patients who can be discharged home. Secondary objectives are to assess the…

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON51219

Source
ToetsingOnline

Brief title
Optimal Acute Admission Ward (Optimal-AAW)

Condition

- Other condition

Synonym
patients in the Acute Admission Ward

Health condition

patiënten die voor verschillende redenen op de acute opname afdeling komen

Research involving
Human

Sponsors and support

Primary sponsor: Rijnstate Ziekenhuis
Source(s) of monetary or material Support: Philips,Ziekenhuis Rijnstate;Arnhem

Intervention

Keyword: acute admission ward, continuous monitoring, deterioration, prediction

Outcome measures

Primary outcome

Study endpoints: The primary endpoint is the number (%) of patients discharged home from acute admission ward.

Secondary outcome

Secondary endpoints are length of stay in the acute admission ward and length of stay in the in-hospital wards, the number (%) of Rapid Response Team calls, Intensive Care Unit admissions and unplanned readmissions to the hospital <30 days. We expect to be able to (retrospectively) predict deterioration and discharge from the AAW and deterioration at home. Facilitators and barriers for implementing a continuous monitoring system with this wearable sensor will be investigated.

Study description

Background summary

Rationale: Hospitals need to make efficient use of beds and healthcare professionals in order to provide optimal care for patients while using the available budget efficiently. Therefore, hospitals aim to hospitalize patients when necessary and discharge patients when possible. However, triaging patients and discharge management is not a trivial task. The upcoming technology of wearable monitoring, whereby patients can be continuously monitored with an unobtrusive vital signs device, might help getting more insight into patients*

health condition and thus help facilitate efficient and effective triaging.

Study objective

Objective: The primary objective is to assess the effects of continuous monitoring of patients in the acute admission ward (AAW) with a wearable sensor on the percentage of patients who can be discharged home. Secondary objectives are to assess the length of stay in the acute admission ward and in the in-hospital wards, as well as the effect on admission to the intensive care unit, rapid response team calls and hospital readmission. The predictive value of algorithms applied to the monitoring data combined with other parameters to detect timely deterioration and predict discharge will be assessed. Facilitators and barriers for implementing such a system will be investigated.

Study design

Study design: This single-center randomized controlled trial (RCT) includes 800 patients admitted to the acute admission ward (AAW). Patients who provided consent will be randomized 1:1 into a group of patients who receive (remote) continuous monitoring for up to 14 days (Monitoring Group n=400) and a group of patients who receive usual monitoring (Usual Care Group n=400). Patients fill in a questionnaire after 14 days, and data including (costs of) healthcare consumption (including rehospitalization) will be collected for up to 30 days from the electronic patient record.

Intervention

Continuous monitoring will be done by means of a wearable patch (Healthdot) that measures vital signs including heart rate and respiratory rate, posture and level of overall physical activity.

Study burden and risks

The Monitoring Group wear the wearable patch (Healthdot) for 14 days. Both monitoring and usual care groups are asked to fill in a short questionnaire after 14 days. Monitoring will be on top of usual care, and thus not add other risks besides a potential skin reaction to the wearable adhesive. Burden and risks are deemed to be low. The main benefit of participation is the potential to be sent home instead of being hospitalized.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients admitted to the Acute Admission Ward of Rijnstate hospital, of whom it is unknown whether they should be discharged home or admitted to the hospital, are included in this randomized controlled study.
In order for a patient to be eligible to participate in this study, the following criteria need to be met:
• admitted to the AAW
• Age >= 18 years
• Able to speak and read Dutch
• Willing and able to provide written informed consent

Exclusion criteria

A patient who meets any of the following criteria will be excluded from participation:
• Not able or willing to wear a wearable sensor on the chest continuously for 14 days
• Planned major surgery in the upcoming 30 days

• At the time of AAW admission already known to be discharged home or admitted to the hospital
• Any skin condition, for example prior rash, discoloration, scars, infection, injury or open wounds at the area (Left lower rib) where the sensor needs to be placed
• Known sensitivity to medical adhesives
• Wearing an active implantable device (e.g. ICD, pacemaker)
• Intend to go to the sauna or go swimming in the upcoming 14 days
• Pregnant or breastfeeding
• Use of creams or lotions that are known to influence the skin at the area where sensor is placed (such as medical and non-medical creams or lotions)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2021
Enrollment:	800
Type:	Anticipated

Medical products/devices used

Generic name:	CE-marked wearable sensor
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	21-07-2021
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL77291.015.21