

System to avoid fall events

Submission date 04/01/2018	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 25/01/2018	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 18/12/2020	Condition category Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

In-patient falls are the most commonly reported patient safety issue in the NHS. Elderly, frail patients are at a particularly high risk of suffering a fall while admitted to hospital. In 2015/2016, more than 247,000 patients suffered an in-patient fall event with more than 10,500 patients over the age of 65 suffered severe harm as the result of a fall. The combined cost to the NHS is £150 million just for this type of injuries. Therefore, this study aims to test a new technology to provide nurses and clinicians with an early warning of situations that are known to frequently cause falls.

Who can participate?

Patients admitted to the ward who are deemed by the ward clinicians to be at risk of falling from the bed

What does the study involve?

The technology uses a non-invasive thermal sensor to measure the patient's position inside the bed. When a patient moves to exit the bed, a notification is sent to a ward nurse, who can respond appropriately to the situation. Should a patient fall out of bed and onto the floor, the technology raises an alarm to the nurses. The study compares the number of fall events recorded in a control phase without the technology with the number of fall events recorded during a test phase with the technology. Each phase lasts 3 months, with a 3-month follow-up.

What are the possible benefits and risks of participating?

The benefit of the study is that the technology may enable nurses to potentially take pre-emptive action before a fall occurs rather than react when a fall has already happened. No direct risk to the participants has been identified. All the hardware is installed after stringent safety precautions to eliminate risks of both voluntary and involuntary misuse of the system during the study.

Where is the study run from?

Royal Lancaster Infirmary (UK)

When is the study starting and how long is it expected to run for?

January 2018 to November 2018

Who is funding the study?
Rinicare Ltd (UK)

Who is the main contact?
1. Søren Udby (public)
2. Margaret Cooper (scientific)

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
999

Study information

Scientific Title

An investigation to explore the feasibility of thermal imaging technology to prevent frail, elderly, and vulnerable patients in hospital wards from suffering preventable, in-patient fall events causing moderate to severe damage

Acronym

SAFE

Study objectives

The study aims to determine the feasibility, suitability, and acceptability of using thermal imaging analysis to produce early warning notifications to prevent at-risk patients from suffering a fall from a bed while in hospital.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Interventional non-randomised study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Patients deemed to be at risk of suffering a fall from a bed due to physical frailty, medication, or mental issues

Interventions

The participants will have a SAFE sensor system installed above their hospital bed as part of this study. The SAFE sensor unit will monitor the participant's position relative to the edge of the bed in real-time. If a dangerous situation is detected by the system, e.g. a frail, elderly patient

sitting on the edge of the bed in preparation to exit the bed, the SAFE system will notify a member of the ward staff to inform them of the situation and take appropriate actions to ensure that the patient exits the bed safely.

The study will compare the number of fall events recorded in a control phase with the number of fall events recorded during the test phase. Each phase is planned for 3 months, with a 3-month follow-up.

Intervention Type

Device

Primary outcome measure

The number of fall events recorded during the test phase and the control phase

Secondary outcome measures

There are no secondary outcome measures

Overall study start date

29/01/2018

Completion date

19/11/2018

Eligibility

Key inclusion criteria

1. Patients admitted to the ward for a duration of no less than 48 hours
2. Patients who are deemed by the ward clinicians to be at risk of falling from the bed due to one or more of the following reasons:
 - 2.1. Frailty due to old age (e.g. 65 years or older)
 - 2.2. Frailty due to medical conditions (e.g. hypotension)
 - 2.3. Frailty due to mental conditions (e.g. dementia)
 - 2.4. Frailty due to physical conditions (e.g. amputation)
 - 2.5. Frailty due to medication(s)

Patients who are able to give informed consent or individuals unable to consent to participation due to a lack of mental capacity their participation needs to be agreed by someone who is independent of the study and who can assess the potential participant's interests in accordance with current legislation and guidance.

This person may be a relative, a carer or an independent representative. These patients are a particularly vulnerable group and their interests must therefore be protected. They should be given the same opportunities to participate in ethically designed research projects as those who do not lack capacity but must not be put at unwarranted risk.

Participant type(s)

Patient

Age group

Mixed

Sex

Both

Target number of participants

90

Key exclusion criteria

1. Patients under 18 years of age
2. Patients in an unconscious state or otherwise unable to move under the own power

Date of first enrolment

02/03/2018

Date of final enrolment

15/08/2018

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Royal Lancaster Infirmary

Ashton Road

Lancaster

United Kingdom

LA1 4RP

Sponsor information

Organisation

Rincare Ltd

Sponsor details

Riverway House

Morecambe Road

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Sponsor type

Industry

Website

Funder(s)

Funder type

Industry

Funder Name

Rinicare Ltd

Results and Publications

Publication and dissemination plan

1. A number of supporting documents have been prepared for this trial:
 - 1.1. The study protocol, currently under review from senior management (due back on Monday 15/01/2018)
 - 1.2. Participant consent form
 - 1.3. Participant information sheet
 - 1.4. Consultee information sheet
 - 1.5. Participant data privacy and protection protocol (in compliance with Rinicare's internal ISO27001 protocols)
 - 1.6. A paper is planned to be published after the completion of the trial for a peer-reviewed journal
2. The plan is to set-up a sub-site for the trial on the www.rinicare.com website with all the publicly available documents.

The intention is to publish an article for a relevant peer-reviewed journal within 3 months of the conclusion of the study. Furthermore, the outcome of the study will be published on Rinicare's website.

Intention to publish date

19/02/2019

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository.

IPD sharing plan summary

Stored in repository