ISRCTN24617143 https://doi.org/10.1186/ISRCTN24617143

System to avoid fall events

Submission date	Recruitment status	[X] Prospectively registered
04/01/2018	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
25/01/2018	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
18/12/2020	Injury, Occupational Diseases, Poisoning	[_] 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 2015/2015, 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

Contact name
Mr Søren Udby

ORCID ID
https://orcid.org/0000-0001-8711-2168

Contact details
Riverway House
Morecambe Road
Lancaster
United Kingdom
LA1 2RX

Type(s)
Scientific

Contact name
Mrs Margaret Cooper

ORCID ID
https://orcid.org/0000-0001-9103-6639

Contact details
Ashton Road
Lancaster
United Kingdom
LA1 4RP

Additional identifiers

Protocol serial number
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

Study type(s)
Prevention

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

Key secondary outcome(s))

There are no secondary outcome measures

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

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

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
United Kingdom

England

Study participating centre
Royal Lancaster Infirmary
Ashton Road
Lancaster
United Kingdom
LA1 4RP

Sponsor information

Organisation
Rinicare Ltd

Funder(s)

Funder type
Industry

Funder Name
Rinicare Ltd

Results and Publications

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes