ISRCTN96565376 https://doi.org/10.1186/ISRCTN96565376

A feasibility study of protective socks against usual care to reduce skin tears in high risk people

Submission date
29/11/2013

Recruitment status
No longer recruiting

Registration date
29/11/2013

Overall study status
Completed

Last Edited
30/10/2017

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Many people develop thin or 'fragile' skin on their lower legs and forearms. This is easily and seriously injured even after a minor knock against furniture, wheelchairs, car bumpers or stair treads. Fragile skin results from the aging process but also the long-term use of steroids, sun exposure and skin diseases. The injuries, 'skin tears', can cover a wide area. Urgent professional attention is required; the injury is very painful and can take a long time to heal. There is also a risk that the injury will develop into a leg ulcer. An ulcer takes a very long time to heal and requires professional help, and in some cases daily attention. Surveys of residents of care homes show that the number of skin tears a resident receives can be as many as five in a year. The people who suffer most from fragile skin are those aged over 70. The UK population in this age group in 2011 was greater than 7 million. We estimate that at least 3 million people may suffer these very unpleasant and confidence-sapping injuries, which result in very high treatment costs for the NHS. There is currently no adequate prevention for skin tears but protective knee-length stockings ('Dermatuff') containing cut-proof Kevlar fibres have now been developed to prevent skin tears to the lower leg. This trial is a feasibility study to find out whether it will be possible to conduct a full definitive trial in the future. The eventual definitive trial will have the aim of determining whether Dermatuff protective socks can prevent lacerations of the lower legs of people who have fragile skin when worn on a daily basis.

Who can participate?
Adults with at-risk skin, mostly elderly people living in care homes, and also people free-living in the community identified from GP databases to suffer from fragile skin due to long-term steroid use.

What does the study involve?
Participants will be randomly allocated into one of two groups. One group will wear the Dermatuff socks and the other will wear their usual clothing for a period of 16 weeks. Any skin tears that occur will be treated as usual but will also be measured and recorded by research nurses. We will look at whether it is possible to recruit participants and care homes to a study such as this, whether people can tolerate wearing the socks, what the dropout rate is and

whether they will complete questionnaire-based outcome measures. We will also look at whether it is feasible to collect the data using research nurses in the community.

What are the possible benefits and risks of participating?
There are potential benefits to being in the trial for the participants. They will all get a bit more attention if they receive a wound, although the treatment of the wounds remains the same as always was (treated by community nurses or a homes own nurses). If the socks work then the group wearing socks may receive fewer skin tears. They also receive three pairs of socks which they can keep at the end of the trial. The people in the control group will receive one pair of socks at the end of the trial. As the study simply involves wearing a pair of socks that look and feel like normal socks and provide minimal compression, this is a low risk study.

Where is the study run from?
The Royal Devon and Exeter Hospital (UK).

When is the study starting and how long is it expected to run for?
The study will run from July 2013 to May 2015.

Who is funding the study?
The study has been funded by an NIHR Research for Patient Benefit (RfPB) grant

Who is the main contact?
Dr Roy Powell
r.j.powell@exeter.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Roy Powell

Contact details
Royal Devon & Exeter Hospital
Barrack Road
Exeter
United Kingdom
EX2 5DW
+44 (0)1392 403048
r.j.powell@exeter.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

14865

Study information

Scientific Title
Randomised controlled trial of protective socks against usual care to reduce skin tears in high risk people: a pilot study

Acronym
STOPCUTS

Study objectives
The study hypothesis for the future definitive trial is that Dermatuff socks will prevent lacerations of the lower legs in people with fragile skin caused by the ageing process or the use of certain medications such as steroids which have the side effect of thinning the skin.

The research question is: in people with fragile skin caused by the ageing process or long-term use of steroids, does the provision of protective socks for daily wear, when compared with care as usual, prevent lacerations of the lower leg?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cornwall and Plymouth Research Ethics Committee, 13/SW/0103

Study design
Randomised interventional prevention trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Primary Care Research Network for England, Generic Health Relevance and Cross Cutting Themes; Subtopic: Not Assigned, Generic Health Relevance (all Subtopics); Disease: All Diseases, Age and ageing

Interventions
Participants in the intervention group will be asked to wear the protective socks during their waking hours every day for a period of 16 weeks, starting from the morning following the day they sign consent, which will be designated as 'Day 1'. Care home staff will be asked to encourage participants to wear the socks and to assist them to put the socks on, if necessary. However, it will be emphasised that if participants become unwilling to wear the socks or want to take them off, they will be free to make that choice. Participants should continue to wear their normal footwear during participation in the study. Participants in the control group will be managed as usual. This includes any routine procedures to reduce the risk of lacerations, but otherwise they will wear their normal clothing.

Follow Up Length: 4 months

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Skin tear-free days: this is the number of days that a participant is free of any skin tears to the lower legs/112 days.

Secondary outcome measures
Secondary outcome measures:
1. Skin lacerations measured (length, breadth and area), and graded to Payne-Martin categories or STAR Skin Tear Classification System
2. Standardised measure of health status (EQ-5D-5L)
3. Disease-specific quality of life measured by Cardiff Wound Impact Schedule
4. Assessment of capability (ICECAP-O)
5. Assessment of fear of falling (Short FES-I)
6. Adverse events caused by the socks
7. Health care resource use

The outcome measures for the current pilot/feasibility study are:
1. Recruitment rate for homes
2. Proportion of participants (home residents) eligible
3. Recruitment rate for participants
4. Attrition and loss to follow up
5. Ascertainment of injuries
6. Completion and completeness of study questionnaires
7. Evaluation of skin-tear classification systems
8. Estimates of the distribution of outcome measures
9. Feasibility of the workload
10. Acceptability of the intervention to participants
11. Acceptability of study participation to participants

Overall study start date
04/07/2013

Completion date

04/05/2015

Eligibility

Key inclusion criteria
Current inclusion criteria as of 17/06/2014:
1. Resident in a care home or living in the community and taking steroids for at least a month
2. Aged 65 years or older
3. Ambulatory and/or wheelchair user able to take part in normal day-to-day activities

Previous inclusion criteria:
1. Resident in a care home
2. Male and female aged 18 years or older, upper age limit 100 years
3. Ambulatory and/or wheelchair user able to take part in daily activities within the care home
4. Having a past medical history of skin tear injuries to legs defined as any reported skin tear injury, regardless of severity, which has occurred within 12 months prior to recruitment

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 90; UK Sample Size: 90

Key exclusion criteria
Current exclusion criteria as of 17/06/2014:
1. Not competent to give informed consent or complete study questionnaires
2. Bedbound
3. Undergoing current treatment for lacerations or ulcers on legs
4. Use of graduated compression stockings/bandaging
5. Scheduled to be admitted to hospital for elective surgery during the study period
6. A participant in other concurrent interventional research which may over-burden the participant or confound data collection

Previous exclusion criteria:
1. Not competent to give informed consent in the opinion of the recruiting nurse
2. Life expectancy less than 6 months
3. Resident is bedbound
4. Resident is being treated for current lacerations or ulcers on their legs
5. Resident is likely to use graduated compression stockings or similar during the intervention period
6. Resident is scheduled to be admitted to hospital for elective surgery during the 16-week trial period

7. Resident is a participant in other concurrent interventional research which may over-burden the resident or confound data collection

Date of first enrolment
04/07/2013

Date of final enrolment
04/05/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Devon & Exeter Hospital
Exeter
United Kingdom
EX2 5DW

Sponsor information

Organisation
Royal Devon and Exeter Foundation Trust (UK)

Sponsor details
Royal Devon & Exeter Hospital
Barrack Road
Exeter
England
United Kingdom
EX2 5DW

Sponsor type
Hospital/treatment centre

Website
http://www.rdehospital.nhs.uk/

ROR
https://ror.org/03085z545

Funder(s)

Funder type
Government

Funder Name
NIHR Research for Patient Benefit (RfPB) (UK) Grant Codes: PB-PG-0711-25129

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/04/2015		Yes	No
Results article	results	17/10/2017		Yes	No
Results article	results	01/12/2017		Yes	No
HRA research summary			28/06/2023	No	No