ISRCTN47349949 https://doi.org/10.1186/ISRCTN47349949

Comparison of cleaning of leg ulcers using pads or wound dressings

Submission date	Recruitment status	[X] Prospectively registered
14/06/2012	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
10/07/2012	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
28/02/2018	Skin and Connective Tissue Diseases	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
We are carrying out a study of 66 people with leg ulcers that require to have their wounds cleaned to remove loose dead tissue to allow healing to begin. The aim of the study is to compare the ease of cleaning wounds with either a wound dressing or a monofilament fibre pad.

Who can participate?
The study aims to recruit about 66 people aged over 18 years old and who have a leg ulcer treated within a leg clinic, Leg Club or at home.

What does the study involve?
Over a period of two weeks participants will be invited to have their leg ulcer cleaned either with a wound dressing or a monofilament fibre pad. Each participant will have their leg ulcer cleaned at weekly intervals with the ulcer photographed before and after each time the wound is cleaned. You will be asked to rate the comfort and any pain associated with the cleaning of your wound each time the wound is cleaned. Whether your wound is cleaned with a wound dressing or a fibre pad will be decided by a process called randomisation, which is like a coin toss.

What are the possible benefits and risks of participating?
There will be no immediate direct benefit to those taking part. However for people who have leg ulcers in the future they may receive benefits in terms of quicker cleaning of their leg ulcer. If you have loose dead tissue within your leg ulcer your nurse will clean this away to allow healing to begin, as such there is no risk involved in participating in the study as you would receive wound cleaning whether or not you participate in the study.

Where is the study run from?
The study has been set up by two investigators well experienced in wound healing and will take place in Cardiff.

When is study starting and how long is it expected to run for?
It is anticipated that recruitment will start late in 2012. Participants will be enrolled on the study for a period of two weeks so it is anticipated that the study will end in mid 2013.

Who is funding the study?
Activa Healthcare Ltd, a UK company who manufacture one of the products to be used to clean your leg ulcer.

Who is the main contact?
Chief investigator's:
Professor Michael Clark, reachmichaelclark@gmail.com
Ms Trudie Young, reachtrudieyoung@gmail.com

Contact information

Type(s)
Scientific

Contact name
Prof Michael Clark

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
8.0

Study information

Scientific Title
A prospective, randomised controlled exploratory study comparing the debridement of sloughy venous leg ulcers undertaking either with a novel debriding agent (monofilament fibre pad) or autolytic debridement using wound dressings

Study objectives
The study will be a prospective, open label randomised controlled, exploratory trial to compare the performance of two techniques used to debride wounds (Debrisoft® debrider and autolytic debridement achieved through the use of wound dressings that maintain a moist environment at the wound surface).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Prospective open label randomised controlled exploratory trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Leg ulcer, chronic wound

Interventions
Treatment arm:
Debrisoft® (Activa Healthcare) consists of monofilament polyester fibres, the reverse side is coated with polyacrylate.
The product is individually packed and sterile (heat treated). Debrisoft® is for single use only and must not be re-sterilized. The product is sterile as long as the packaging remains unopened and undamaged.

Indications:
In wound bed preparation, Debrisoft® is intended as a rapid, highly effective and safe debridement method in the treatment of superficial wounds and their surrounding skin, for example in cases of diabetic ulcers, arterial and venous ulcers, pressure ulcers and postoperative wounds healing by second intention

Debrisoft® can also be used for absorbing exudate, cellular debris and keratosis during debridement. Debrisoft® is gentle on intact tissue.

There are also very good results with Debrisoft® in the treatment of wounds with major keratotic and necrotic coatings, provided these wounds have previously been treated with autolytic debridement [8, 11].

Application:
1. Remove the existing wound dressing.
2. Debridement procedure:
2.1. Soak Debrisoft® with e.g. water or saline, according to local guidelines.

2.2. Wipe the wound surface gently with the soft fibre side of the moistened Debrisoft® (without any extensive pressure).
3. Repeat the procedure with a fresh Debrisoft® to cleanse the peri ulcer skin and any areas of the lower limb covered with hyperkeratosis.
4. Apply emollient if required to the peri ulcer skin and lower limb.
5. Apply a new wound dressing.

Precautions:
Debrisoft® must not be used as a wound dressing.
The product must not be used in case of known intolerance or an allergy against one or more of its constituents.

Control arm:

Intrasite Conformable (Smith & Nephew Healthcare) is a hydrogel wound dressing consisting of a non-woven dressing wilh a clear amorphous hydrogel. The hydrogel contains a modified carboxy-methyl cellulose polymer, propylene glycol and water.

Mode of action:
Intrasite Conformable promotes natural debrIdement through autolysis by gently rehydrating necrotic tissue. It also loosens and absorbs slough and exudate. Intrasite Conformable provides a moist wound environment. It does not harm viable tissue or skIn surrounding wounds. lntrasite Conformable faciltates the gentle packing of cavity wounds to allow them to heal from the base, as well as aidIng application of gel to awkward areas.

Indications:
Intrasite Conformable Is indicated for use In open wounds e.g. pressure ulcers, surgical wounds healing by secondary Intention, malignant wounds, shallow wounds, excorIated skin and radiation burns.

Application:
For shallow wounds, apply at least two layers of the dresslng: Ensure res!dual gel Is removed prior to radiation therapy.
1. Clean the wound with sterile saline solution.
2. Apply the dressIng as required to loosely fill or cover the wound.
3. Cover with a secondary dressing e.g. film dressing or absorbent dressing.
4. To change the dressing, sImply remove gently with forceps and irrigate the wound with sterile saline. Ensure that all dressIngs are removed. It Is recommended that the dressing Is changed at least every three days.

Precautions
Known sensitivity to Intrasite Conformable or any of Its Ingredients. Intrasite Conformable should be used with care in the vicinity of the eyes. AvoId Ingestion. Avoid use on cracked nIpples.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

1. To compare the performance of two debridement methods upon
1.1. Changes in the appearance of the wound bed will be based upon quantitative size and colour analysis of photographs taken before debridement and ten 10 minutes after debridement has occurred with these measures repeated weekly for 2 weeks.
1.2. The wound size within 14 days of treatment

Secondary outcome measures
1. The removal of hyperkeratosis
2. The relative costs of each treatment option
3. Narrative reports from clinical staff and subjects regarding their experience of the two interventions
4. Any pain and discomfort associated with the use of the interventions rated using visual analogue scales

Overall study start date
01/10/2012

Completion date
31/03/2013

Eligibility

Key inclusion criteria
1. Age: At least 18 years of age
2. Sex: Males and females (provided they are not pregnant)
3. Patients with a leg ulcer (surface area no larger than 40cm^2) of any aetiology and not older than one year. Leg ulcer at least 50% covered with devitalised tissue that is not fixed dry necrotic tissue or tenacious slough.
4. The patient is able to understand the trial and is willing to give written consent to the trial

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
66

Key exclusion criteria
1. Leg ulcer larger than 40cm^2 and older than one year
2. Leg ulcer covered by fixed dry necrotic tissue or tenacious slough
3. Leg ulcer not covered to 50% of its surface area with devitalised tissue (slough)
4. Known allergy to components of the Debrisoft® debrider or wound dressing

5. Use of the debrider is too painful and patient cannot tolerate its mechanical action
6. Malignant wound
7. Recent deep venous thrombosis or venous surgery
8. Progressive neoplastic lesion treated by radiotherapy or chemotherapy
9. Prolonged treatment with immunosuppressive agents or high dose corticosteroids
10. Patients who have participated in this trial previously
11. Patients who have participated in a pharmacological clinical trial within the past six months
12. Patients who are unable to understand the aims and objectives of the trial
13. Patients with a known history of non concordance with medical treatment
14. Females who are pregnant

Date of first enrolment
01/10/2012

Date of final enrolment
31/03/2013

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Creative Consultancy & Research
Cardiff
United Kingdom
CF10 4RE

Sponsor information

Organisation
Activa Healthcare Ltd (UK)

Sponsor details
1 Lancaster Park
Burton-on-Trent
United Kingdom
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Sponsor type
Industry

Website

http://www.activahealthcare.co.uk/

Funder(s)

Funder type
Industry

Funder Name
Activa Healthcare Ltd (uk)

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