An open randomised comparative study to evaluate the performance of AQUACEL® Extra* in Venous Leg Ulcers

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON37546

Source
ToetsingOnline

Brief title
Assessment of AQUACEL® Extra* on Venous Leg Ulcers

Condition

- Other condition
- Skin vascular abnormalities

Synonym
venous leg ulcers, venous ulcers

Health condition

venous disease

Research involving
Human

Sponsors and support

Primary sponsor: Kaltostat: ConvaTec; Mepilex: Molnlyke Health Care AB
Source(s) of monetary or material Support: ConvaTec Ltd

Intervention

Keyword: Dressings, Venous leg ulcer

Outcome measures

Primary outcome

Exudate management:

- wear time

- % dressings achieving a 7 day wear time

- Time to achieve a 7 day wear time

- Condition of the peri-ulcer skin

Secondary outcome

Besides that the following will be investigated as well: Safety, Ulcer

improvement, Progress towards healing, Pain, Comfort, Ease of Use, Dressing

utilisation and costs

Study description

Background summary

Hydrofiber® dressings have played an increasingly important role in the management of wounds since their introduction to the market in 1994. Exudate management in wound care is very important. Hydrofiber dressings are known for their ability to provide effective moisture balance, and their gelling properties provide excellent control of exudate (Okan 2007). From the literature it is shown that AQUACEL® (a sterile dressing made from a non-woven sheet of sodium carboxymethylcellulose (NaCMC). cellulose) yarns) achieves a mean wear time of three to four days in the management of venous leg ulcers (Harding 2001, Armstrong 1997, Clinical Evaluation Report, August 2011). In

vitro studies have demonstrated that AQUACEL® Extra* (AQUACEL® Extra* (a soft conformable flat sheet of non-woven fabric sandwiched into two layers and stitch-bonded together using Lyocel (Tencel* regenerated cellulose) yarns.) is 39% more absorbent than AQUACEL®. It is anticipated that this increased capacity will enable a longer wear time in a clinical scenario. A comparative study is proposed to assess the performance of the AQUACEL® Extra* dressing when compared to AQUACEL®.

Study objective

The primary objective of the above study is to evaluate the wear time AQUACEL® Extra* when compared to AQUACEL® in subjects with venous leg ulcers. Stratification will be done for exudate (moderate vs highd) and type of dressing (AQUACEL®Extra* vsAQUACEL®)

Study design

The study is randomised; therefore your patient will be treated with either the AQUACEL® Extra* or AQUACEL® for 4 weeks.

Your patients wound will be dressed according to clinical need with the aim to leave the dressing in place for 7 days.

At each dressing change wounds will be evaluated and details related to the wound status and condition of the wound bed will be recorded. Acetate tracings and wound photographs will also be taken.

Intervention

The study is randomised; therefore your patient will be treated with either the AQUACEL® Extra* or AQUACEL® for 4 weeks. Stratification will be done for exudate (moderate vs highd) and type of dressing (AQUACEL®Extra* vsAQUACEL®).

Study burden and risks

Both AQUACEL® Extra* and AQUACEL® provide a moist environment that supports the growth of new blood vessels, occasionally the delicate newly formed blood vessels may produce a blood stained wound fluid.
Possible allergic reactions e.g. skin rash and irritation.
There is a possibility that the dressing*s ability to remove dead tissue and debris may result in the wound appearing larger of the first few dressing changes. Rarely irritation of the skin surrounding the ulcer may occur.
There are no specific adverse events known for these dressings.

Study will last 4 weeks, 30 minutes per visit. Number of visits is dependent on

dressing changes.

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

The following subjects may be included in the study:;•Subjects over 18 years, willing and able to provide written informed consent.
•Subjects who have an ankle to brachial pressure index (ABPI) of 0.8 or greater
•Subjects who have a venous leg ulcer (i.e. CEAP classification of C6 1) with duration less than 24 months
•Subjects whose ulcer is no larger than 2cm x 11cm
•Subjects who have only one ulcer on the index leg
•Subjects* whose index leg ulcer has a moderate to heavy level of exudate (a definition of exudate levels will be provided).

•Subjects whose index (study) leg is currently being treated with compression therapy and whose leg oedema is under control
•Subjects who are willing and able to comply with the requirements of the clinical investigation plan in relation to the dressing/compression regime and the ability to attend dressing changes as required.

Exclusion criteria

The following subjects must not be included into the study:;•Subjects with a history of skin sensitivity to any of the components of the study dressings.
•Subjects whose wounds are considered clinically infected at baseline
•Subjects whose leg is oedematous (level of oedema TBC)
•Subjects whose leg ulcers are malignant, or who have had recent deep venous thrombosis or venous surgery within the last 3 months.
•Subjects who have progressive neoplastic lesion treated by radiotherapy or chemotherapy, or on-going treatment with immunosuppressive agents
•Subjects exhibiting any other medical condition which, according to the Investigator, justifies the subject*s exclusion from the study
•Subjects who have participated in a clinical study within the past month.

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-07-2012
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO Date:	26-04-2012
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	10-07-2012
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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	NL39382.028.12