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Performance of the medical device LHAC1 (hyaluronic acid - collagenase) for the management of chronic venous ulcers

Submission date 23/01/2012	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 22/02/2012	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 09/09/2014	**Condition category** Circulatory System	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Venous ulcers are extremely common, affecting about 1% of the worlds population, and their impact on cost of healthcare and the lives of the subjects is quite significant. This study aims to assess the performance and tolerability of the medical device LHAC1 (hyaluronic acid - collagenase) for the management of chronic venous ulcers.

Who can participate?
Patients between 18 and 80 years of age with chronic venous ulcers.

What does the study involve?
At baseline, all subjects were enrolled to receive LHAC1. A layer of about 2 mm of LHAC1 should be applied on the wound bed once a day. Study treatment continued until complete wound debridement or for a maximum of 20 days.

What are the possible benefits and risks of participating?
All participants will receive the described treatment, which may reduce necrotic area of the wound bed. There are no known serious risks to participants.

Where is the study run from?
This study has been conducted in four different centers in Romania: Spitalul Universitar Elias, Spitalul Clinic Dermato-Venerice, Spitalul Clinic Municipal and Spitalul Clinic Judetean Craiova.

When is the study starting and how long is it expected to run for?
The study ran from February to November 2010.

Who is funding the study?
Fidia Farmaceutici S.p.A. (Italy).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Prot. LHAC1-05

Study information

Scientific Title
Multicenter, open label, clinical trial on the performance and tolerability of the medical device LHAC1 (hyaluronic acid - collagenase) for the management of chronic venous ulcers

Study objectives
To evaluate the performance and tolerability of the LHAC1 medical device for the excision of chronic venous ulcers in the wound bed preparation phase.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Romanian Health Ministry, 26/11/2008, ref: 12 din 28.12.2009

Study design
Multicenter open-label study

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

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
Chronic venous ulcers

Interventions
A layer of about 2 mm thickness of LHAC1 (HA-Collagenase) was applied on the wound bed once a day.
Treatment continued until complete wound debridement or for a maximum period of 20 days.
Prior to application the wound was cleansed of debris by gently rubbing with a gauze pad saturated with normal saline solution, or with the desired cleansing agent compatible with collagenase. Dry wounds had to be moistened with physiological saline (0.9% NaCl) or glucose solution prior to treatment. The treatment had to be covered using a non-occlusive dressing to assure the contact with the wound surface.

Five visits were scheduled:
Visit one: enrolment and start of therapy
Visit two: during study treatment
Visit three:during study treatment
Visit four: during study treatment
Visit five: patient final evaluation

At each visit, the following assessments were performed:
1. Physical examination
2. Vital signs
3. Device performance evaluation
4. Concomitant medications/treatments
5. Safety evaluation
6. Compliance
7. Device application

These were measured at day 0 (baseline), day 5 (visit 1), day 10 (visit 2), day 15 (visit 3), day 20 (visit 4 - final visit).

At visit five, we also performed laboratory tests.

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure
Number of subjects (%) with complete debridement (final debridement or final visit vs baseline) evaluated by using the following five-points scale:
1=100% reduction
2= presence of less than 25% of necrotic tissue
3= presence of 26% to 50% of necrotic tissue
4= presence of 51% to 74% of necrotic tissue
5= presence of 75% to 100% of necrotic tissue
where the points 1 and 2 were considered a complete debridement rating.
This scale was used for the final data analysis and on the basis of measurements obtained during the trial by tracing the wound necrotic area by grid.

Secondary outcome measures
1. Reduction percentage of necrotic area
2. Status of the wound bed (non-necrotic/clean area) and periwound skin
3. Overall final judgments

Overall study start date
02/02/2010

Completion date
18/11/2010

Eligibility

Key inclusion criteria
1. Both sexes, all ethnic backgrounds, both ambulatory and hospitalized
2. Subjects between 18 and 80 years of age
3. Subjects with a diagnosis of chronic venous ulcers (CEAP classification: C6) with areas (or scattered areas) of necrosis (non-viable soft tissue/slough) more than 40%
4. Subjects who have a venous leg ulcer of at least 6 months duration
5. Subjects who have a target wound which is between 2 cm squared to 25 cm squared in area at the baseline assessment
6. Subjects, who are, in the opinion of the Investigator, able to understand this study, cooperate with the study procedures and are willing to return to the centre for all the required visits
7. Subjects who have given their written informed consent in accordance with provisions of pertinent excerpt from the Declaration of Helsinki (revised October 2008) and the Romanian laws

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100 patients

Key exclusion criteria
1. Subjects with venous leg ulcer with presence of black eschar
2. Subjects who have exposed bone, tendon or fascia visible around the target wound
3. Subjects who have an Ankle Brachial Pressure Index lower than 0.8 (ABPI/ABI< 0.8), measured by Doppler sonography, absent pulses and peripheral arterial disease
4. Subjects using occlusive wound dressings. The elastocompressive bandages are allowed
5. Concomitant use of local antibiotics, hydrogels, hydrocolloids (the administration of oral antibiotics in presence of infection is allowed)
6. Concomitant use of detergents, hexachlorophene, acid solutions, antiseptics containing heavy metal ions (such as mercury, silver, cobalt, magnesium and manganese), or soaks containing metal ions or acidic solutions (such as Burow's aluminium acetate solution)
7. Concomitant use of disinfectants containing quaternary ammonium
8. Subjects with a known hypersensitivity to collagenase or hyaluronic acid
9. Immunocompromised subjects; known seropositivity to human immunodeficiency virus (HIV)
10. Subjects affected by severe renal, dismetabolic or hepatic failure which represents a risk to the subjects
11. Presence of underlying medical conditions that might interfere with study completion, e.g. end-stage malignant disease, unstable diabetes mellitus, aplastic anaemia, sclerodermia, severe obesity (Body Mass Index > 35), cachexia and recent burns
12. Participation in any other study involving investigational or marketed products concomitantly or within one month prior to study entrance
13. A history of alcoholism, treatment abuse, psychological or other emotional problems that could invalidate informed consent or limit the subject's compliance with protocol requirements
14. Females who are pregnant, lactating or who have not reached menopause and are not abstinent or practising an acceptable means of birth control as determined by the Investigator for the duration of the study
15. Necessity to have a concomitant therapy with any treatment mentioned in the restrictions
16. Subjects unlikely to be compliant/cooperative during the study, in the judgment of the Investigator

Date of first enrolment
02/02/2010

Date of final enrolment
18/11/2010

Locations

Countries of recruitment
Romania

Study participating centre
Spitalul Universitar Elias
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Sponsor information

Organisation
Fidia Pharmaceutical [Fidia Farmaceutici S.p.A.] (Italy)

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Sponsor type
Industry

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ROR
https://ror.org/00dy5wm60

Funder(s)

Funder type
Industry

Funder Name
Fidia Pharmaceutical [Fidia Farmaceutici S.p.A.] (Italy)

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