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Treatment of non-healing ulcers with a dressing based on a innovative nanomaterial

Submission date	Recruitment status
21/07/2017	No longer recruiting
Registration date	**Overall study status**
01/08/2017	Completed
Last Edited	**Condition category**
20/09/2023	Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol

Background and study aims
Chronic ulcers are defined as ulcers that do not heal in six to nine weeks.This type of ulcer is a big health problem all over the world, affecting the life of patients and the health care system. Wound dressings based on a dense fibrillary network (fibers) made of biosynthetic cellulose (BC), such as eiratex® have been proposed to be a good alternative to the different types of dressings that are currently used to treat this type of ulcers. This is due to their similarity to collagen in skin (the protein in the skin that gives skin strength and elasticity). However, traditional BC has been problematic on infected ulcers since fluids as exudate can be trapped under the dressing. The aim of this study is to examine if a wound dressing based on eiratex® can facilitate the healing of the wound and overcome the problems related to the use of the traditional BC.

Who can participate?
Adults aged 62 to 85 who have a chronic lower limb wound (ulcer) that has not healed after six weeks.

What does the study involve?
Participants are treated with the eiratex®-based wound dressing. The dressing is applied on the ulcers after surgical removal of the damaged area or tissue, when applicable. The wounds are examined every second day by the attending physician during the first week, and then once per week until final healing. When the wound started to heal, the dressing should be found to adhere to the wound, typically within two days from the start of treatment. In case of lack of improvement of the wound healing, a new debridement was carried out and a new eiratex® membrane was applied to the wound. Once the dressing adhered it is not removed from the wound until it spontaneously fell off. An examination by the attending physician is then performed to assess wound healing.

What are the possible benefits and risks of participating?
There are no benefits or risks with participating.

Where is the study run from?
Ewecare AB (Sweden)

When is the study starting and how long is it expected to run for?
January 2016 to May 2017

Who is funding the study?
S2Medical AB (Sweden)

Who is the main contact?
Mr Tobias Sivler
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

Protocol serial number
1101

Study information

Scientific Title
A clinical trial on patients with non-healing ulcers treated with a modified version of a biosynthetic cellulose named eiratex: Effects on the healing rate, healing time and treatment costs compared to a saline-soaked gauze and other wound dressings.

Study objectives
Wound dressing based on eiratex® could facilitate the healing of the wound and overcome the problems related to the use of the traditional BC.

Ethics approval required
Old ethics approval format

Ethics approval(s)
As the the product is registed in registered in Sweden as medical device and is CE-marked, according to Swedish law, ethical approval is not necessary for the study. The study itself was not an experimental procedure.The patients were treated and their follow-up data collected

only after informed consent. All patient information was blinded so that no information can be back traced to individual patients.

Study design
Observational cross-sectional cohort study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Patients with chronic lower-extremity venous ulcers or traumatic ulcers were object of this trial

Interventions
The eiratex® dressing was applied on the wound after surgical debridement, where applicable. The wounds are examined every second day by the attending physician during the first week, and then once per week until final healing.

When the wound started to heal, the dressing was found to adhere to the wound, typically within two days from initiation of treatment. In case of lack of improvement of the wound healing, a new debridement was carried out and a new eiratex® membrane was applied to the wound. In three patients clinical signs of infection were seen. Once the dressing adhered it was not removed from the wound until it spontaneously fell off. An examination by the attending physician was then performed to assess wound healing.

At each treatment visit, information regarding adverse events, medications and other aspects of care since the last visit was acquired. All wounds were photographed before treatment and at each follow-up visit after treatment.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Healing time is measured by visual examination from the medical doctor. At each treatment visit, information regarding adverse events, medications and other aspects of care since the last visit was acquired.

Key secondary outcome(s))
1. Frequency of dressing changes are measured by counting the total number of dressings used during the treatment for each patient, divided by the healing time (in weeks)
2. Number of dressings used are measured by the doctor for each patient. The number of dressings used is related to the number needed to heal the wound

Completion date
30/05/2017

Eligibility

Key inclusion criteria
1. Chronic lower limb wounds that were not healed after 6 weeks from the initial injury
2. Treated with eiratex® for the whole treatment
3. Non-infected and infected ulcers
4. Aged from 62 to 85 years old

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
8

Key exclusion criteria
1. Patients with exposure of bone, muscle, ligaments, or tendons
2. Patient with mental disorders were excluded to guarantee a conscious agreement to the participation in this study

Date of first enrolment
01/02/2016

Date of final enrolment
01/03/2017

Locations

Countries of recruitment
Sweden

Study participating centre
Ewecare AB
Hejdegatan 68
Linköping
Sweden
58243

Sponsor information

Organisation
Ewecare AB

Funder(s)

Funder type
Industry

Funder Name
S2Medical AB

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Petter Silver, petter.sivler@s2m.se. Data about the outcomes of the study are stored as excel files and will only be shared upon request.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		29/03/2018	20/09/2023	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes