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# Investigation of a novel formulation with a Lactic Acid Bacterial microbiome on chronic ulcers

**Submission date**
12/12/2017

**Recruitment status**
No longer recruiting

**Registration date**
18/12/2017

**Overall study status**
Completed

**Last Edited**
18/12/2017

**Condition category**
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

## Plain English summary of protocol

Background and study aims
Chronic wounds cause significant suffering and cost healthcare systems throughout the world billions every year. Current treatments such as antimicrobials vary in their effectiveness and traditional antibiotics have become less practical with increasing antibiotic resistance. Reports on the type of bacteria causing chronic wounds vary, but it is recognized that a main cause of non-healing in chronic wounds is the presence of many different bacteria. A broad-spectrum, ecological, and easy-to-use treatment is therefore essential for the future of wound management. The participants of this study will test a new treatment composed of a new mixture of friendly bacteria and honey, to investigate if this treatment has any effect on the healing progress of wounds in patients suffering from these during many years and also to delineate if the treatment has any adverse effects. The aim of this study is to see if this new treatment may have a positive effect on wounds by healing them in a fester manner and therefore such a treatment may be a good choice for future wound management being more ecological and with a broad-spectrum ability.

Who can participate?
Adults aged 18 and older who have a venous leg ulcer.

What does the study involve?
Participants have their wound assessed and classified as complex or simple. Participants then receive a formulation of Lactic Acid Bacteria in a matrix of sterilised honey place on the wound. The wound is covered with two dressings: A hydro-fibre dressing applied over the formulation and an outer dressing to keep the formulation on place. The formation is applied twice a week for six weeks. Participants provide blood samples to measure blood glucose before the formulation is applied and 30 minutes after at the beginning and the end of the study.

What are the possible benefits and risks of participating?
A benefit may be that the treatment may heal the wounds faster than conventional treatments. A direct risk may be a rise of blood glucose level cause by the application of the honey containing formulation.

Where is the study run from?
1. Blekinge Wound Healing Centre (Sweden)
2. Sønderborg Wound Healing Centre (Denmark)
3. Infection Clinic Danderyd Hospital (Sweden)
4. Bensårcentrum Skaraborgs Hospital (Sweden)

When is the study starting and how long is it expected to run for?
September 2014 to September 2015

Who is funding the study?
1. Ekhaga Foundation (Sweden)
2. The Capio Research Foundation (Sweden)
3. The Swedish Research Council (VR) (Sweden)
4. STRAMA (Sweden)

Who is the main contact?
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# Contact information

### Type(s)
Scientific

### Contact name
Mrs Alejandra Vásquez

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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
Dnr: 2014/795

# Study information

### Scientific Title
Proof of concept study to investigate if a novel formulation with a Lactic Acid Bacterial microbiome has an effect on Venous Leg Ulcers

### Study objectives
Can a novel microbiome composed of lactic acid bacteria have an effect on chronic leg ulcers?

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Ethical Committee Lund, Sweden, 09/12/2014, ref: Ethical application Dnr: 2014/795

### Study design
Proof-of -concept multicentre study

### Primary study design
Interventional

### Secondary study design
Non randomised study

### 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 leg ulcers

### Interventions
Participants included in the study are older than 18 years old, with diagnosed venous leg ulcers (ankle brachial pressure index (ABPI), more than 0.8, and clinical signs of venous insufficiency, with a wound duration of minimum 6 weeks.

Physicians assess the participants and the wounds prior to the start of the study to confirm diagnosis and suitability for inclusion. The wounds are classified as complex or simple.

The interventions comprised of applying a formulation (consisted of Lactic Acid Bacteria in a matrix of sterilized honey) onto the wounds. The wounds were then covered with two dressings; a hydro-fibre dressing (Aquacel®, Convatec, Sweden) applied over the formulation, and an outer dressing (Eclypse®, Advancis, UK), to keep the formulation on place. The formulation is applied twice a week during the duration of the study, which is six weeks. In addition, blood glucose

samples are taken before the application of the formulation and 30 minutes after application of the formulation. Blood glucose is investigated at inclusion and at the end of the study.

A registered nurse fills in the protocols at three times: at week 0 (before treatment), week 3 (middle point) and week 6 (after treatment). The protocol included information about haemoglobin, smoking habits, overall morbidity, and aspects of the ulcer including wound duration, pain, ulcer size, percentage of fibrinous tissue and granulation, exudation and odour.

All patients continued with their regular compression bandage during the duration of the study.

A registered nurse measured wounds metrically and photos were taken of all wounds prior to the study and at completion of the study at week 6.

### Intervention Type
Biological/Vaccine

### Primary outcome measure
Progression of healing of wounds was measured following reduction of wound surface area using a digital planimeter (Visitrak, manufactured in the UK for Smith & Nephew Medical Limited, Hull) at inclusion and at the end of the study period.

### Secondary outcome measures
1. Total bacterial load variation in wound samples was measured by calculating viable bacterial counts from isolates aerobically grown on blood agar at week 0 (before treatment), week 3 (middle point) and week 6 (after treatment)
2. Bacterial identification was investigated by using two methods, identification using protein patterns in Maldi-Tof and DNA sequencing of the 16S rRNA gene at week 0 (before treatment), week 3 (middle point) and week 6 (after treatment)
3. Rise in blood glucose was measured using blood samples at inclusion and at the end of the study period

### Overall study start date
01/09/2014

### Completion date
01/09/2015

## Eligibility

### Key inclusion criteria
1. Patients >18 years old
2. Diagnosed venous leg ulcers (ankle brachial pressure index (ABPI) >0.8 and clinical signs of venous insufficiency
3. Informed consent

### Participant type(s)
Patient

### Age group
Adult

**Lower age limit**
18 Years

**Sex**
Both

**Target number of participants**
16 patients

**Key exclusion criteria**
Patients treated with systemic antibiotics or who had cognitive or linguistic impairment are excluded.

**Date of first enrolment**
15/01/2015

**Date of final enrolment**
01/08/2015

# Locations

**Countries of recruitment**
Denmark

Sweden

**Study participating centre**
**Blekinge Wound Healing Centre**
Blekinge Hospital
Karlshamn
Sweden
SE-374 80

**Study participating centre**
**Sønderborg Wound Healing Centre**
Sønderjylland Hospital
Sønderborg
Denmark
DK-6400

**Study participating centre**
**Infection Clinic Danderyd Hospital**
Danderyd
Sweden
SE-18288

**Study participating centre**
**Bensårcentrum Skaraborgs Hospital**
Skövde
Sweden
SE-54185

# Sponsor information

**Organisation**
Lund University

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**Sponsor type**
University/education

**ROR**
https://ror.org/012a77v79

# Funder(s)

**Funder type**
Charity

**Funder Name**
Ekhaga Foundation

**Funder Name**
The Capio Research Foundation

**Funder Name**
The Swedish Research Council (VR)

**Funder Name**
STRAMA

# Results and Publications

**Publication and dissemination plan**
The proof of concept study will be described in a research article. We intend to publish the results as soon as possible, as the study is already performed and completed.

**Intention to publish date**
01/12/2018

**Individual participant data (IPD) sharing plan**
The current data sharing plans for the current study are unknown and will be made available at a later date.

**IPD sharing plan summary**
Data sharing statement to be made available at a later date