

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

Submission date 12/12/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 18/12/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 18/12/2017	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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 faster 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 placed 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 formulation 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 caused 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?

Mrs Alejandra Vásquez
alejandra.vasquez@med.lu.se

Contact information

Type(s)

Scientific

Contact name

Mrs Alejandra Vásquez

ORCID ID

<https://orcid.org/0000-0002-1777-9554>

Contact details

Lund University
Section of Medical Microbiology
Sölvegatan 23
Lund
Sweden
SE-223 63
+46 462221694
alejandra.vasquez@med.lu.se

Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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 (Eclipse®, 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(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

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

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