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Study of two local wound therapy concepts

Submission date	Recruitment status	[_] Prospectively registered
11/12/2023	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
31/01/2024	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
22/01/2024	Injury, Occupational Diseases, Poisoning	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
This study is a national research project where we'll be comparing two different ways of treating wounds to see which one is better at cleaning them. The study is designed to be fair and unbiased, and it won't involve any new treatments or placebos. We're focusing on how well each approach reduces the amount of slough in wounds.

Who can participate?
All people age 18 to 85 years with chronic wounds of the following entities:
Ulcus cruris venosum
Ulcus cruris mixtum
Diabetic neuropathic foot ulceration

What does the study involve?
The study comprises 28 days of randomised treatment with either Actimaris solution and gel or Microdacyn solution and gel.
Further wound treatment is based on the standard of the centre. The treatment corresponds to the valid standards of care.

What are the possible benefits and risks of participating?
By participating in the study, the patient receives an unrestricted causal wound-specific and local treatment that fully corresponds to the current state of the art and medical knowledge.
Participation will contribute to a systematic collection of data on the effectiveness and tolerability of appropriate products for wound irrigation and wound cleansing (solutions and gels) in a direct comparison.
As this is an established and particularly gentle wound cleansing procedure, no adverse effects are to be expected from these activities. Due to the use of the study products within the scope of their certified intended purpose, no particular risks are associated with participation in the study.

Where is the study run from?
Landesklinikum Wiener Neustadt (Austria)
Wound Competence Centre (Austria)

When is the study starting and how long is expected to run for?

Who is funding the study?
ActiMaris AG (Switzerland)

Who is the main contact?
Dr Thomas Eberlein, thomaseberlein@hotmail.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Protocol serial number
GS1-EK-3/183/2021

Study information

Scientific Title
Demonstration of the physical wound cleansing performance of Actimaris sensitive solution and gel as well as Microdacyn solution and gel based on the reduction of wound debris

Study objectives
Objective demonstration of the physical wound cleansing performance of Actimaris sensitive wound irrigation solution and Actimaris gel as well as Microdacyn Solution and Microdacyn Gel. Hypothesis: Both wound irrigation solutions are able to remove yellowish fibrinoid coatings / debris by half the surface area within 4 weeks.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 18/10/2021, Ethikkommission Für Das Bundesland Niederösterreich (Landhausplatz 1, St. Pölten, 3109, Austria; +43 2742/9005-12731; post.ethikkommission@noel.gv), ref: GS1-EK-3 /183/2021

Primary study design
Interventional

Study design
Randomized investigator-blinded non-interventional non-placebo-controlled national clinical comparative study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Objective demonstration of the physical wound cleansing performance of two local therapy concepts

Interventions
Application of two local therapy concepts (Actimaris sensitive wound irrigation solution and Actimaris gel or Microdacyn solution and Microdacyn gel) to demonstrate the physical wound cleansing performance (whereby it is assumed that both concepts are able to reduce yellowish fibrinous adherent coatings by half the area within 4 weeks).

Randomisation is carried out by random selection into two groups using sealed, completely opaque envelopes.
Patients are treated with either Actmaris solution and gel or Microdacyn solution and gel.

The following methodology applies to both study arms:
After removing the dressing, the wet phase is carried out (according to Gerhard Kammerlander):
Application of at least two gauze compresses, saturated wet with the test product "solution" and covered with at least one non-soaked gauze compress
15 minutes application time
Remove the compresses and clean the wound mechanically with gauze compresses moistened with the respective test product.
The "wound gel" test product is then applied to the wound surface and covered with a hydrofibre product (Aquacel extra or Biosorb Gelling Fibre Dressing)
The choice of wound covering is made according to exudation and the decision of the attending physician (best standard of care of the centre)
The total treatment period is 28 days.

Intervention Type
Other

Primary outcome(s)
The physical cleansing performance (reduction of the wound coating over time) of two therapy concepts is determined over a period of 28 treatment days; measured via quantitative image analysis and clinical blinded assessment at the beginning, after 7, 14, 21 and 28 days of treatment.

Key secondary outcome(s)
1. Tolerability (subjective assessment by patient and practitioner [pain/burning/itching] using VAS score at the beginning, after 7, 14, 21 and 28 days of treatment.
2. Odour reduction (subjective assessment by the practitioner using the four-stage odour assessment scoring tool (OAST)) at the beginning, after 7, 14, 21 and 28 days of treatment.

3. Reduction of signs of inflammation (subjective assessment by the practitioner) using the documentation tool at the beginning, after 7, 14, 21 and 28 days of treatment.
4. Clinical biofilm detection (existence and reduction) by means of parameters (existence of a continuous, slimy, milky-transparent film on the wound), after 7, 14, 21 and 28 days of treatment.

Completion date
30/06/2024

Eligibility

Key inclusion criteria
Patients with chronic wounds:
1. Ulcus cruris venosum
2. Ulcus cruris mixtum: KADI (ankle-brachial index ≥ 0.7)
3. Diabetic neuropathic foot ulcer (Wagner-Armstrong 1A and 3A) if they are weakly to heavily exuding and superficial to max. 2 cm deep
4. Wound surface area min. 1 cm^2
5. Wound age at least 8 weeks
6. Causal cause diagnosed and (re-)treated
7. Wounds show at least a slight odour in the clinical assessment ("slight odour" according to the Odour Assessment Scoring Tool or "odour 1" according to the AVLON scale)
8. At least 50 % of the wound surface shows yellowish (fibrinoid) adherent debris at the time of study inclusion

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
85 Years

Sex
All

Key exclusion criteria
1. Pure PAOD-related ulceration
2. Purely lymphological entities
3. Acute wounds
4. Chronic wounds with signs of infection
5. Age <18, > 85 years

6. Allergy to one or more of the substances used
7. Pregnancy and breastfeeding
8. Inability to adequately participate in the study

Date of first enrolment
15/04/2021

Date of final enrolment
30/06/2024

Locations

Countries of recruitment
Austria

Study participating centre
Landesklinikum Wiener Neustadt
Corvinusring 3-5
Wiener Neustadt
Austria
2700

Sponsor information

Organisation
ActiMaris AG Switzerland

Funder(s)

Funder type
Industry

Funder Name
ActiMaris AG, Switzerland

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during the current study will be available upon request from Dr Thomas Eberlein (thomaseberlein@hotmail.com).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.0	20/07/2020	22/01/2024	No	No