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Use of Nexodyn in the local standard therapy of chronic infected ulcers

Submission date
22/03/2016

Recruitment status
No longer recruiting

Registration date
01/04/2016

Overall study status
Completed

Last Edited
21/07/2021

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol

Background and study aims
A chronic ulcer is a long-lasting sore that takes a long time to heal (longer than around 4 weeks). Some may tale a very long time to heal, if at all. If the ulcer has become infected (with a bacterial infection) this can worsen the overall clinical picture. The aim of this study is to investigate whether using Nexodyn, a solution that contains hypochlorous acid, leads to an improvement in healing of chronic infected ulcers. Nexodyn is a spray solution intended for use in the debridement (removing dead/infected tissue), irrigation (washing) and moistening of wounds, ulcers, cuts, abrasions, burns and other lesions. Through reducing the amount of microorganisms and contributing to a moist environment, it enables the body to perform its own healing process.

Who can participate?
Adults (aged at least 18) with a chronic venous or atypical ulcer.

What does the study involve?
All participants are treated with Nexodyn spray solution twice a day plus an inert secondary dressing for 4 weeks. Patients with venous ulcers are also allowed to use compression stockings as a part of the recommended therapeutic approach of the underlying disease. The ulcers are assessed every week throughout the study period.

What are the possible benefits and risks of participating?
Participants may find that they benefit from their ulcer shrinking in size and a reduction in the amount of pain they experience from the wound. However, there may be some risks which at the moment are unpredictable.

Where is the study run from?
University of Pisa (Italy)

When is the study starting and how long is it expected to run for?
December 2014 to January 2017

Who is funding the study?
APR Applied Pharma Research SA

Who is the main contact?
Dr Anna Barassi

Contact information

Type(s)
Scientific

Contact name
Dr Anna Barassi

Contact details
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Additional identifiers

Protocol serial number
AOS/CW/01/2014

Study information

Scientific Title
Use of Nexodyn in the local standard therapy of chronic infected ulcers: an exploratory study

Study objectives
The aim of this exploratory study is to confirm that Nexodyn, a newly developed European CE-marked medical device containing hypochlorous acid, contributes to the improvement of the wound healing process of infected chronic wounds of different aetiology (venous, and atypical ulcers).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committe for clinical trials CEAVNO (North-west VASTA area, Tuscany, Italy), 24/07/2014, ref: 308/2014

Primary study design
Interventional

Study design
Open-label non-comparative monocentric interventional study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic wounds

Interventions
All patients will receive a local treatment with Nexodyn twice daily plus an inert secondary dressing only for 4 weeks. Patients with venous ulcers will be allowed to use compression stockings to help venous return as a part of the recommended therapeutic approach of the underlying disease (venous insufficiency).
The study will end after the 4-week treatment with Nexodyn.

Intervention Type
Device

Primary outcome(s)
Percentage of patients achieving a Wound Bed Preparation (WBP) score of A1, A2, A3 or B1, measured by visually evaluating the type of tissues and the amount of exudate in the wound, during the 4-week treatment with Nexodyn

Key secondary outcome(s)
1. Change of the WBP score at weeks 1, 2, 3 and 4 versus baseline, measured by visually evaluating the type of tissues and the amount of exudate in the wound.
2. Change of ulcer area and depth at weeks 1, 2, 3 and 4 versus baseline, measured by means of the STAR ARANZ System (a wound imaging, 3D measurement and documentation system providing accurate wound information)
3. Change of wound bed pH at weeks 1, 2, 3 and 4 versus baseline, measured by means of a non-invasive potentiometric method (a pH meter)
4. Change in the relative presence of coloured wound areas [white/black (L*), red/green (b*) and yellow/blue (c*)] at weeks 1, 2, 3 and 4 versus baseline, measured by a colorimeter (Cielab System) performing skin colour assessment
5. Change in wound-related pain at weeks 1, 2, 3 and 4 versus baseline, measured using the visual analogue score (VAS)
6. Patient’s acceptance of Nexodyn, evaluated immediately after each application according to a 4-point scale (from 1 = Very comfortable/relief sensation to 4 = Very uncomfortable/pain sensation)
7. Change of patients’ quality of life and perception of health outcomes at week 4 versus baseline, measured with the Short Form 12 (SF-12).
8. Caregiver’s assessment of product usability, measured by a 4-point scale (from 1 = excellent overall convenience to 4 = poor overall convenience) at week 4
9. Local tolerability and safety

Completion date
31/01/2017

Eligibility

Key inclusion criteria
1. Patients legally able to give their written informed consent to the trial
2. Male and female patients aged ≥18 years with no limitation of race
3. Presence of a chronic wound (onset at least 4 weeks before enrolment) presenting the following characteristics:

3.1. Presence of infection (contamination, colonization and critical colonization) diagnosed according to clinical signs
3.2. Total ulcer size ≥5 cm2 involving the derma, without visible exposure of tendon or bone.
3.3. WBP score equal to B2, B3, C1, C2 or C3
4. Ankle Brachial Pressure Index (ABPI) ≥0.60 in the affected limb, for venous ulcers
5. Patients with clinical signs and laboratory results of atypical ulcer etiology
6. Patients who have access, for the duration of the study, to reliable outpatient care (self, family member, nursing staff, regular visits at hospital, etc.)
7. Patients who will be available for the entire study period, and will be able and willing to adhere to protocol requirements

Participants may have multiple ulcers but only ONE will be considered the target ulcer that must be identified prior the inclusion in the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
38

Key exclusion criteria
1. Patients with wounds characterized by the presence of necrotic dry eschar
2. Pregnant or lactating women, and women of childbearing potential not following an adequate contraceptive method
3. Diagnosis or suspect of septicemia, immunodeficiency and, in patients with venous ulcers, diagnosis or suspect of autoimmune diseases
4. Severe chronic diseases or conditions (class IV cardiac failure, uncontrolled arterial hypertension, hepatic failure, renal failure, malignancy in advanced phase, any myelopathy, anemia, chemotherapy).
5. Patients on ongoing therapy with immunosuppressive drugs or who used immunosuppressive drugs in the 4 weeks previous to study entry, except the subjects with atypical ulcer etiology under immunosuppressive maintenance therapy.
6. Patients on ongoing therapy with systemic antibiotics or who used systemic antibiotics in the 4 weeks previous to study entry.
7. Patients on ongoing therapy with drugs or medical devices active on the ulcer evolution, such as, but not limited to, collagens, hydrogels, hydrocolloids, etc.
8. Any condition that, in the opinion of the investigator, would preclude adherence or compliance to the study (e.g. chronic alcoholism, illicit drug abuse/dependence, personality disorder, relevant cognitive impairment).

9. Known allergy or intolerance to ingredients or excipients of the formulation of Nexodyn.
10. Participation, within the past 3 months prior to the start of the study, in any clinical trial, including individuals previously enrolled in this study.

Date of first enrolment
20/01/2015

Date of final enrolment
31/12/2016

Locations

Countries of recruitment
Italy

Study participating centre
University of Pisa (Università di Pisa)
Unità Operativa Dermatologia Universitaria
Dipartimento Medicina Clinica e Sperimentale
via Roma 67
Pisa
Italy
56126

Sponsor information

Organisation
APR Applied Pharma Research SA

ROR
https://ror.org/05c2q0q08

Funder(s)

Funder type
Industry

Funder Name
APR Applied Pharma Research SA

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 Patrizia Mascagni (p.mascagni@hippocrates-research.it). Satistical outputs, CRFs and electronic database are made available to September 2018 for one year. Consent from the participants are already obtained but only anonymised data are available.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		29/01/2021	21/07/2021	No	No