

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

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 01/04/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 21/07/2021	<b>Condition category</b> Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> 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 take 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

c/o APR Applied Pharma Research s.a.

Via Corti 5

Balerna

Switzerland

CH - 6828

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

### Study design

Open-label non-comparative monocentric interventional 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 contact details to request a participant information sheet

**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 measure**

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

**Secondary outcome measures**

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

**Overall study start date**

01/12/2014

**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  $\geq 18$  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  $\geq 5$  cm<sup>2</sup> 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)  $\geq 0.60$  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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

60

**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

**Sponsor details**

Via Corti 5  
Balerna  
Switzerland  
CH - 6828

**Sponsor type**

Industry

**Website**

<http://www.apr.ch>

**ROR**

<https://ror.org/05c2q0q08>

**Funder(s)****Funder type**

Industry

**Funder Name**

APR Applied Pharma Research SA

**Results and Publications****Publication and dissemination plan**

The data of the completed trial are planned to be published in an international peer-reviewed journal soon after the completion of the trial. Data are also planned to be disseminated as abstract/poster or potentially in the form of oral presentation in an international congress. In case of an anticipated closure of the study, the publication will be done if the investigator considers the data clinically meaningful.

**Intention to publish date**

01/01/2022

**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](mailto:p.mascagni@hippocrates-research.it)). Statistical 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?
<a href="#">Basic results</a>		29/01/2021	21/07/2021	No	No