A prospective, non-interventional multicenter study, performed in patients with burns, to evaluate efficacy and safety aspects of NexoBrid in clinical practice

First published: 09/03/2018

Last updated: 02/07/2024

Study | Finalised

Administrative details

EU PAS number

EUPAS23046

Study ID

29535

DARWIN EU® study

No

Study countries

Germany

Study description

This study will be a prospective, non-interventional study, performed in patients with burns, to evaluate safety and efficacy aspects of NexoBrid in clinical practice. Documentation of the treatment outcomes will be performed by using the case report form as well as photographing the burns before and after application of NexoBrid.

Study status

Finalised

Research institutions and networks

Institutions

Sana Klinikum Duisburg

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Institution

BG Klinik Ludwigshafen Ludwig-Guttmann-Straße 13, 67071 Ludwigshafen/Rhein, Germany

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Thomas Pierson

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 01/04/2014

Study start date
Actual: 01/05/2014

Date of final study report
Planned: 15/01/2019

Actual: 15/01/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

MediWound Germany GmbH

Study protocol

Studienprotokoll NexoBrid_07NOV2014_Final.pdf (38.14 KB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Other study registration identification numbers and links

OS-BURN2014

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Application of NexoBrid in clinical practice, efficacy of training program, gathering of data on outcome of treatment and therapeutic experience with NexoBrid in clinical practice.

Data collection methods:

Primary data collection

Main study objective:

To gather data about the application of NexoBrid in real clinical practice, to evaluate if application is performed in accordance to approval. The study should prove the efficacy of MediWounds' comprehensive training program at implementation of NexoBrid. Another objective of this study is to gather data regarding outcomes of treatment and therapeutic experience with NexoBrid in clinical practice.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Prospective, non-interventional study, performed in patients with burns, to evaluate safety and efficacy aspects of NexoBrid in clinical practice

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(D03BA03) bromelains

bromelains

Population studied

Short description of the study population

Any patient who was treated with NexoBrid in order to treat burn wounds.

The criteria for the use of NexoBrid as per marketing authorization of NexoBrid were:

1. Males and females; ≥ 18 years of age,
2. Deep partial- and full-thickness thermal burns
3. A total wound area of not more than 15% TBSA

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)

Special population of interest

Other

Special population of interest, other

Patients with burns

Estimated number of subjects

200

Study design details

Data analysis plan

Detailed data analysis will be provided in the final study report.

Documents

Study results

End of Study Report OSBURN_15_JAN_2019.pdf (136.49 KB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Other

Data sources (types), other

Documentation of the treatment outcomes will be performed by using the case report form as well as photographing the burns before and after application of NexoBrid.

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown