

# An international, observational retrospective data collection study assessing efficacy of applied risk minimisation measures in burn patients treated with NexoBrid (NexoPASS)

**First published:** 08/05/2017

**Last updated:** 31/03/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS18751

---

### Study ID

31843

---

### DARWIN EU® study

No

---

### Study countries

 Belgium

 Germany

 Poland

 Slovakia

 Spain

 Sweden

---

### **Study description**

The study will consist of a retrospective chart review performed in specialised centres in the EU using NexoBrid. It is planned to include about 160 patients. The main objective will be the comparison of incidence rates for pain and pyrexia with the incidence rates observed within the clinical trials after implementation of risk minimisation measures. The study will further assess the incidence of wound infections, compliance with the risk minimisation activities, time to wound closure and prescribing patterns such as the amount of patients treated off-label and other endpoints.

---

### **Study status**

Finalised

## Research institutions and networks

### Institutions

[MediWound Ltd.](#)

[Multiple centres: 15 centres are involved in the study](#)

## Contact details

### Study institution contact

Aya Ben Yaakov ayaby@mediwound.com

Study contact

[ayaby@mediwound.com](mailto:ayaby@mediwound.com)

### Primary lead investigator

Keren David-Zarbiv

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 14/03/2017

---

### Study start date

Planned: 01/07/2017

Actual: 01/01/2018

---

### Date of final study report

Planned: 30/06/2019

Actual: 12/09/2019

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

MediWound LTD

## Study protocol

[NexoPASS Protocol MW2013-06-01\\_Version 6\\_24Apr2017\\_final\\_signed.pdf](#)  
(633.6 KB)

[NexoPASS Protocol MW2013-06-01\\_Version 6.1\\_21June2017\\_Signed.pdf](#) (791.52 KB)

## Regulatory

### **Was the study required by a regulatory body?**

Yes

---

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

EU RMP category 3 (required)

## Other study registration identification numbers and links

Product reference: EMEA/H/C/002246 Procedure number: MEA003.4

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Disease /health condition  
Human medicinal product

---

**Study type:**

Non-interventional study

---

**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Data collection methods:**

Secondary use of data

---

**Main study objective:**

Assessing the effectiveness of the risk minimisation activities and their effect on the incidence rate of identified risks

## Study Design

**Non-interventional study design**

Other

---

**Non-interventional study design, other**

Retrospective chart review

## Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(D03BA03) bromelains

bromelains

---

### **Medical condition to be studied**

Burns second degree

Burns third degree

## Population studied

### **Short description of the study population**

All patients who received NexoBrid treatment according to the hospital routine in participating specialist burn centres which received the training program for implementation of risk minimization procedures within the frame of regular product release.

---

### **Age groups**

- Term newborn infants (0 - 27 days)
  - Infants and toddlers (28 days - 23 months)
  - Children (2 to < 12 years)
  - Adolescents (12 to < 18 years)
  - Adults (18 to < 46 years)
  - Adults (46 to < 65 years)
  - Adults (65 to < 75 years)
  - Adults (75 to < 85 years)
  - Adults (85 years and over)
- 

### **Estimated number of subjects**

160

## Study design details

## **Outcomes**

Comparison of the incidence rates of the identified risks pain and pyrexia reported in a pre-defined time frames from treatment in routine clinical practice from product launch to those obtained in clinical trials after implementation of risk minimisation activities. - The compliance of the physician with the instructions from Educational Material relate to the risk minimization activities (i.e. whether antibacterial soaking before and after NexoBrid application performed, adequate pain management/administration of analgesia/sedation medication prescribed to the patient before applying NexoBrid and before removing NexoBrid).- Incidence of wound infection AEs

---

## **Data analysis plan**

All measured variables and derived parameters will be listed individually in listings. Tables using descriptive statistics will be provided for the primary and secondary variables as well as for other variables concerning demographics and baseline characteristics.

## Documents

### **Study results**

[MediWound\\_MW20130601\\_CSR-FINAL-Signed.pdf](#) (1.55 MB)

---

## 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

Existing data before signature of informed consent starting from injury and data collected during treatment until wound closure as documented in the medical charts of the patients will be used.

## 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