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

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Study contact

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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/002246Procedure 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