NEXOBRID Belgian registry: Prospective Assessment of Efficacy of NexoBrid in the treatment of Adult Patients with deep 2nd degree and 3rd degree dermal burns in Belgium.

First published: 27/11/2017

Last updated: 31/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS21681

Study ID

21682

DARWIN EU® study

No

Study countries

☐ Belgium

Study status

Finalised

Research institutions and networks

Institutions

MediWound Germany

ZNA Campus Stuivenberg Antwerp

Contact details

Study institution contact

Monstrey Stanislas Stan.Monstrey@UGent.be

Study contact

Stan.Monstrey@UGent.be

Primary lead investigator

Monstrey Stanislas

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 15/02/2016

Study start date
Actual: 01/03/2016

Date of final study report
Actual: 17/10/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

MediWound Germany

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

The overall study objective is a population based prospective assessment of efficacy of NexoBrid in Belgium.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Non-interventional patient registry

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(D03BA03) bromelains

bromelains

Population studied

Short description of the study population

Adult patients with deep 2nd and 3rd degree thermal burns in need of eschar removal/debridement.

Age groups

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

Estimated number of subjects

23

Study design details

Outcomes

Aassessment of efficacy of debridement/eschar removal using NexoBrid to treat adult patients with deep dermal and full thickness burns, To evaluate the depth of the burns treated with NexoBrid,To document the area treated as % TBSA,To document the usage of NexoBrid, To document the evolution of wound until wound closure.

Data analysis plan

The NexoBrid registry is descriptive in nature for hypothesis generation. All analyses will be descriptive in nature and performed by means of SAS 9.4Further details are given in the SAP

Documents

Study results

171017 CSR_Nexobrid_FINAL.pdf (1.29 MB)

Data management

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)

Disease registry

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