An Open Label Multi-Center Extension Study to Evaluate the Long-term Safety of Zorblisa (SD-101-6.0) in Patients with Epidermolysis Bullosa

Published: 02-03-2015
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The aim is to assess the long-term safety of topical use of ZORBLISA in patients with Epidermolysis Bullosa (EB).

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Epidermal and dermal conditions
Study type	Interventional

Summary

ID

NL-OMON43935

Source
ToetsingOnline

Brief title
SD-006 Open Label Extension Study

Condition

- Epidermal and dermal conditions

Synonym
Inherited connective tissue disease; Genetic skin disorder

Research involving
Human

Sponsors and support

Primary sponsor: Scioderm Inc.
Source(s) of monetary or material Support: Scioderm Inc.

Intervention

Keyword: Junctional non Herlitz EB, Open Label Extension, Simplex Epidermolysis Bullosa (EB) Recessive Dystrophic EB

Outcome measures

Primary outcome

The primary objective is to demonstrate the longterm safety of ZORBLISA in

patients, with Simplex, Recessive Dystrophic, and Junctional non-Herlitz

Epidermolysis Bullosa.

Secondary outcome

The secondary objectives are to assess the efficacy of ZORBLISA in terms of the

change in Body Surface Area (BSA) of lesional skin and wound

burden; as well as closure of unhealed target wounds from the SD-005 study.

Study description

Background summary

Epidermolysis Bullosa (EB) is a rare group of inherited disorders that typically manifest at birth as blistering and lesion formation on the skin and, in some cases, the epithelial lining of other organs, in response to little or no apparant trauma. In consequence, the skin is extremely fragile which can result in shearing of the skin, causing a high risk of infection. All forms of EB are both debilitating and life threatening. There are no standard of care products available to treat the dermal manifestations of EB, and there is no approved drug for EB in either Europe or United States. There have been numerous studies published on potential treatments for skin manifestations associated with EB. No controlled studies showed clinical benefit of any therapy. Newer exploratory treatments including skin grafts, bioengineered skin

products, and gene therapy have been unsuccessful to date. In an open label study patients treated with SD-101 cream showed significant improvements in the complete healing of lesions, clinically meaningful reductions in the extent of total skin surface involvement with active disease, and reduced pain and itching. The aim is to assess the long-term safety of topical use of ZORBLISA in patients with Epidermolysis Bullosa (EB).

Study objective

The aim is to assess the long-term safety of topical use of ZORBLISA in patients with Epidermolysis Bullosa (EB).

Study design

This is an open label, multi-center extension study to assess the long-term safety of topically applied ZORBLISA in Patients with Simplex, Recessive Dystrophic, and Junctional non-Herlitz Epidermolysis Bullosa.

Intervention

ZORBLISA will be applied topically, once a day, to the entire body for a period of 630 days.

Study burden and risks

In a previous study with SD-101, some cases of mild redness of the skin have been reported after application of SD-101 cream. Furthermore, patients will be asked to complete pain and itching scales, and diaries. All patients will have to use study cream SD-101 once daily for 630 days and visit the hospital/clinic more frequently.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

1. Informed Consent form signed by the subject or subject's legal representative; if the subject
is under the age of 18 but capable of providing assent, signed assent from the subject.
2. Subject (or caretaker) must be willing to comply with all protocol requirements.
3. Patients who completed the SD-005 study (on study drug at Visit 5).

Exclusion criteria

1. Patients who do not meet the entry criteria outlined above.
2. Pregnancy or breastfeeding during the study. (A urine pregnancy test will be performed at the final visit for SD-005 for female patients of childbearing potential)
3. Females of childbearing potential who are not abstinent or not practicing a medically acceptable method of contraception

Study design

Design

Study phase:	3
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-10-2015
Enrollment:	14
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Zorblisa
Generic name:	ALLANTOIN

Ethics review

Approved WMO Date:	02-03-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	07-09-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	01-04-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	20-06-2016

Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	10-05-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	30-05-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	06-07-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	26-07-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2014-005679-96-NL
CCMO	NL52446.042.15