# Clinical trial results:
# An Observational Study Providing 12 Months of Safety Follow-Up from First Exposure to HP802-247 in Subjects Who Participated in Study 802-247-09-032 (EU)

## Summary

| | |
|---|---|
| EudraCT number | 2013-000949-39 |
| Trial protocol | HU PL DE BE CZ |
| Global end of trial date | 20 November 2015 |

### Results information

| | |
|---|---|
| Result version number | v1 (current) |
| This version publication date | 27 October 2016 |
| First version publication date | 27 October 2016 |

## Trial information

### Trial identification

| | |
|---|---|
| Sponsor protocol code | 802-247-09-033 |

### Additional study identifiers

| | |
|---|---|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT01970657 |
| WHO universal trial number (UTN) | - |

Notes:

### Sponsors

| | |
|---|---|
| Sponsor organisation name | Smith & Nephew, Inc. |
| Sponsor organisation address | 3909 Hulen street, Fort Worth, Texas, United States, 76107 |
| Public contact | Jaime Dickerson, PhD<br>VP Global Medical and Clinical Affairs, Smith & Nephew, Inc<br>3909 Hulen Street<br>Fort Worth, TX 76107<br>United States, +1 8173023914, |
| Scientific contact | Jaime Dickerson, PhD<br>VP Global Medical and Clinical Affairs, Smith & Nephew, Inc<br>3909 Hulen Street<br>Fort Worth, TX 76107<br>United States, +1 8173023914, |

Notes:

### Paediatric regulatory details

| | |
|---|---|
| Is trial part of an agreed paediatric investigation plan (PIP) | No |
| Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial? | No |
| Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial? | No |

Notes:

## Results analysis stage

| | |
|---|---|
| Analysis stage | Final |
| Date of interim/final analysis | 23 December 2015 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 20 November 2015 |
| Global end of trial reached? | Yes |
| Global end of trial date | 20 November 2015 |
| Was the trial ended prematurely? | No |

Notes:

## General information about the trial

Main objective of the trial:

The primary objective of this study was to assess new adverse events and ongoing adverse events not resolved in subjects who were exposed to an Investigational Medicinal Product in the 802-247-09-032 trial (EudraCT number 2012-003286-18)

Protection of trial subjects:

Only subjects that met all the study inclusion criteria and none of the exclusion criteria were to be entered in the study.
All subjects were informed about the study and provided the opportunity to ask questions. Subjects, or their legal representatives, read, signed, and dated the IEC-approved consent form before taking part in any study activity.

Background therapy: -

Evidence for comparator: -

| | |
|---|---|
| Actual start date of recruitment | 27 April 2014 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | No |

Notes:

## Population of trial subjects

### Subjects enrolled per country

| | |
|---|---|
| Country: Number of subjects enrolled | Poland: 101 |
| Country: Number of subjects enrolled | Belgium: 4 |
| Country: Number of subjects enrolled | Czech Republic: 38 |
| Country: Number of subjects enrolled | Germany: 37 |
| Country: Number of subjects enrolled | Hungary: 41 |
| Worldwide total number of subjects | 221 |
| EEA total number of subjects | 221 |

Notes:

### Subjects enrolled per age group

| | |
|---|---|
| In utero | 0 |
| Preterm newborn - gestational age < 37 wk | 0 |
| Newborns (0-27 days) | 0 |
| Infants and toddlers (28 days-23 months) | 0 |

| | |
|---|---|
| Children (2-11 years) | 0 |
| Adolescents (12-17 years) | 0 |
| Adults (18-64 years) | 97 |
| From 65 to 84 years | 108 |
| 85 years and over | 16 |

## Subject disposition

### Recruitment

Recruitment details:

Subjects were enrolled based on participation in the 802-247-09-032 trial (EudraCT number 2012-003286-18), evidenced by randomization in and completion (or discontinuation) of that trial and having received at least one application of test article.

### Pre-assignment

Screening details:

The present study allowed subjects to transition immediately upon exit from the 802-247-09-032 trial (EudraCT number 2012-003286-18).

### Period 1

| | |
|---|---|
| Period 1 title | Overall Trial (overall period) |
| Is this the baseline period? | Yes |
| Allocation method | Randomised - controlled |
| Blinding used | Double blind |
| Roles blinded | Subject, Investigator, Monitor, Data analyst, Carer |

Blinding implementation details:

The group assignment was retained from the 802-247-09-032 trial (EudraCT number 2012-003286-18) and remained blinded to everyone, with the exception of the Sponsor, until the completion of this trial to prevent any bias being introduced into the assessments.

### Arms

| | |
|---|---|
| Are arms mutually exclusive? | Yes |
| **Arm title** | HP802-247 (in 802-247-09-032 trial) |

Arm description:

Patients who received HP802-247 as treatment in the 802-247-09-032 trial (EudraCT number 2012-003286-18)

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | HP802-247 |
| Investigational medicinal product code | HP802-247 |
| Other name | |
| Pharmaceutical forms | Cutaneous spray |
| Routes of administration | Topical use |

Dosage and administration details:

The product was administered in the 802-247-09-032 trial (EudraCT number 2012-003286-18). 260 µL of HP802-247 containing 0.5x106 cells/mL was administered every 14 days and Vehicle on the alternate weeks.

| | |
|---|---|
| **Arm title** | Vehicle (in 802-247-09-032 trial) |

Arm description:

Patients who received the Vehicle as treatment in the 802-247-09-032 trial (EudraCT number 2012-003286-18)

| | |
|---|---|
| Arm type | Control |
| Investigational medicinal product name | Vehicle |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Cutaneous spray |
| Routes of administration | Topical use |

Dosage and administration details:

The product was administered in the 802-247-09-032 trial (EudraCT number 2012-003286-18). 260µL of the vehicle formulation (fibrinogen solution and thrombin solution without cells) was administered every 7 days.

| **Number of subjects in period 1** | HP802-247 (in 802-247-09-032 trial) | Vehicle (in 802-247-09-032 trial) |
|---|---|---|
| Started | 115 | 106 |
| Completed | 98 | 95 |
| Not completed | 17 | 11 |
| Consent withdrawn by subject | 2 | 3 |
| Adverse events | 2 | 3 |
| Lost to follow-up | 7 | 2 |
| Scheduling error | 5 | 3 |
| Protocol deviation | 1 | - |

## Baseline characteristics

| Reporting groups | |
|---|---|
| Reporting group title | HP802-247 (in 802-247-09-032 trial) |
| Reporting group description: | |
| Patients who received HP802-247 as treatment in the 802-247-09-032 trial (EudraCT number 2012-003286-18) | |
| Reporting group title | Vehicle (in 802-247-09-032 trial) |
| Reporting group description: | |
| Patients who received the Vehicle as treatment in the 802-247-09-032 trial (EudraCT number 2012-003286-18) | |

| Reporting group values | HP802-247 (in 802-247-09-032 trial) | Vehicle (in 802-247-09-032 trial) | Total |
|---|---|---|---|
| Number of subjects | 115 | 106 | 221 |
| Age categorical<br>Units: Subjects | | | |
| In utero | 0 | 0 | 0 |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | 0 |
| Newborns (0-27 days) | 0 | 0 | 0 |
| Infants and toddlers (28 days-23 months) | 0 | 0 | 0 |
| Children (2-11 years) | 0 | 0 | 0 |
| Adolescents (12-17 years) | 0 | 0 | 0 |
| Adults (18-64 years) | 55 | 42 | 97 |
| From 65-84 years | 53 | 55 | 108 |
| 85 years and over | 7 | 9 | 16 |
| Age continuous<br>Units: years | | | |
| arithmetic mean | 64.8 | 67.7 | |
| standard deviation | ± 13 | ± 12.8 | - |
| Gender categorical<br>Units: Subjects | | | |
| Female | 68 | 56 | 124 |
| Male | 47 | 50 | 97 |

| Subject analysis sets | |
|---|---|
| Subject analysis set title | HP802-247 (in 802-247-09-032 trial) - ITT |
| Subject analysis set type | Intention-to-treat |
| Subject analysis set description: | |
| All enrolled subjects in the HP802-247 arm who had at least one assessment of ulcer status post-enrollment. The ITT population was the primary dataset for the evaluation of efficacy persistence. | |
| Subject analysis set title | Vehicle (in 802-247-09-032 trial) - ITT |
| Subject analysis set type | Intention-to-treat |
| Subject analysis set description: | |
| All enrolled subjects in the Vehicle arm who had at least one assessment of ulcer status post-enrollment. The ITT population was the primary dataset for the evaluation of efficacy persistence. | |

| **Reporting group values** | HP802-247 (in 802-247-09-032 trial) - ITT | Vehicle (in 802-247-09-032 trial) - ITT | |
|---|---|---|---|
| Number of subjects | 112 | 105 | |
| Age categorical<br>Units: Subjects | | | |
| In utero | 0 | 0 | |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | |
| Newborns (0-27 days) | 0 | 0 | |
| Infants and toddlers (28 days-23 months) | 0 | 0 | |
| Children (2-11 years) | 0 | 0 | |
| Adolescents (12-17 years) | 0 | 0 | |
| Adults (18-64 years) | 52 | 42 | |
| From 65-84 years | 53 | 55 | |
| 85 years and over | 7 | 8 | |
| Age continuous<br>Units: years | | | |
| arithmetic mean | 65 | 67.5 | |
| standard deviation | ± 13.1 | ± 12.8 | |
| Gender categorical<br>Units: Subjects | | | |
| Female | 66 | 56 | |
| Male | 46 | 49 | |

## End points

### End points reporting groups

| | |
|---|---|
| Reporting group title | HP802-247 (in 802-247-09-032 trial) |
| Reporting group description: | |
| Patients who received HP802-247 as treatment in the 802-247-09-032 trial (EudraCT number 2012-003286-18) | |
| Reporting group title | Vehicle (in 802-247-09-032 trial) |
| Reporting group description: | |
| Patients who received the Vehicle as treatment in the 802-247-09-032 trial (EudraCT number 2012-003286-18) | |
| Subject analysis set title | HP802-247 (in 802-247-09-032 trial) - ITT |
| Subject analysis set type | Intention-to-treat |
| Subject analysis set description: | |
| All enrolled subjects in the HP802-247 arm who had at least one assessment of ulcer status post-enrollment. The ITT population was the primary dataset for the evaluation of efficacy persistence. | |
| Subject analysis set title | Vehicle (in 802-247-09-032 trial) - ITT |
| Subject analysis set type | Intention-to-treat |
| Subject analysis set description: | |
| All enrolled subjects in the Vehicle arm who had at least one assessment of ulcer status post-enrollment. The ITT population was the primary dataset for the evaluation of efficacy persistence. | |

### Primary: Proportion of subjects with persistent ulcer closure over the duration of the study for those subjects who had achieved confirmed ulcer closure in the 802-247-09-032 study.

| | |
|---|---|
| End point title | Proportion of subjects with persistent ulcer closure over the duration of the study for those subjects who had achieved confirmed ulcer closure in the 802-247-09-032 study. |
| End point description: | |
| End point type | Primary |
| End point timeframe: | |
| From Week 08 to End of follow-up | |

| End point values | HP802-247 (in 802-247-09-032 trial) - ITT | Vehicle (in 802-247-09-032 trial) - ITT | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 57[1] | 57[2] | | |
| Units: Percentage of Subjects | | | | |
| number (not applicable) | | | | |
| Ulcer not closed | 12.3 | 10.5 | | |
| Ulcer closed | 87.7 | 89.5 | | |

Notes:

[1] - Only subjects with confirmed closure from the prior study were included in this end point

[2] - Only subjects with confirmed closure from the prior study were included in this end point

### Statistical analyses

| **Statistical analysis title** | Durable Ulcer Closure at End of Follow-Up Visit |
|---|---|
| Comparison groups | Vehicle (in 802-247-09-032 trial) - ITT v HP802-247 (in 802-247-09-032 trial) - ITT |
| Number of subjects included in analysis | 114 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 1 [3] |
| Method | Fisher exact |

Notes:

[3] - p-value was based on the Fisher's Exact Test

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

The evaluation of safety was conducted from the Enrollment visit (Visit 0) until the End of follow-up visit.

Adverse event reporting additional description:

The evaluation of safety included analysis of new test article-related events, as well as continued follow-up of those adverse events that originated in the 802-247-09-032 trial (EudraCT number 2012-003286-18)

| | |
|---|---|
| Assessment type | Systematic |

### Dictionary used

| | |
|---|---|
| Dictionary name | MedDRA |
| Dictionary version | 12.0 |

### Reporting groups

| | |
|---|---|
| Reporting group title | HP802-247 (in 802-247-09-032 trial) |

Reporting group description:

Subjects enrolled in the current study and who recieved HP802-247 as treatment in the 802-247-09-032 trial (EudraCT number 2012-003286-18)

| | |
|---|---|
| Reporting group title | Vehicle (in 802-247-09-032 trial) |

Reporting group description:

Subjects enrolled in the current study and who recieved the Vehicle as treatment in the 802-247-09-032 trial (EudraCT number 2012-003286-18)

| Serious adverse events | HP802-247 (in 802-247-09-032 trial) | Vehicle (in 802-247-09-032 trial) | |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 15 / 115 (13.04%) | 15 / 106 (14.15%) | |
| number of deaths (all causes) | 3 | 2 | |
| number of deaths resulting from adverse events | | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Acute myeloid leukaemia | | | |
| subjects affected / exposed | 1 / 115 (0.87%) | 0 / 106 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Pancreatic neoplasm | | | |
| subjects affected / exposed | 0 / 115 (0.00%) | 1 / 106 (0.94%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Penile cancer | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 115 (0.00%) | 1 / 106 (0.94%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Squamous cell carcinoma | | | |
| subjects affected / exposed | 0 / 115 (0.00%) | 1 / 106 (0.94%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular disorders | | | |
| Haematoma | | | |
| subjects affected / exposed | 0 / 115 (0.00%) | 1 / 106 (0.94%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypertension | | | |
| subjects affected / exposed | 0 / 115 (0.00%) | 1 / 106 (0.94%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Surgical and medical procedures | | | |
| Cardiac pacemaker replacement | | | |
| subjects affected / exposed | 1 / 115 (0.87%) | 0 / 106 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| General disorders and administration site conditions | | | |
| Death | | | |
| subjects affected / exposed | 0 / 115 (0.00%) | 2 / 106 (1.89%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 2 | |
| Impaired healing | | | |
| subjects affected / exposed | 2 / 115 (1.74%) | 0 / 106 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Reproductive system and breast disorders | | | |
| Prostatitis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 115 (0.87%) | 0 / 106 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Dyspnoea | | | |
| subjects affected / exposed | 0 / 115 (0.00%) | 1 / 106 (0.94%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Psychiatric disorders | | | |
| Depression | | | |
| subjects affected / exposed | 0 / 115 (0.00%) | 1 / 106 (0.94%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Injury, poisoning and procedural complications | | | |
| Contusion | | | |
| subjects affected / exposed | 1 / 115 (0.87%) | 0 / 106 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Femoral neck fracture | | | |
| subjects affected / exposed | 1 / 115 (0.87%) | 0 / 106 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Femur fracture | | | |
| subjects affected / exposed | 1 / 115 (0.87%) | 0 / 106 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hip fracture | | | |
| subjects affected / exposed | 0 / 115 (0.00%) | 1 / 106 (0.94%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal column injury | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 115 (0.00%) | 1 / 106 (0.94%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thermal burn | | | |
| subjects affected / exposed | 1 / 115 (0.87%) | 0 / 106 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac disorders | | | |
| Angina pectoris | | | |
| subjects affected / exposed | 0 / 115 (0.00%) | 1 / 106 (0.94%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bundle branch block left | | | |
| subjects affected / exposed | 0 / 115 (0.00%) | 1 / 106 (0.94%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac failure | | | |
| subjects affected / exposed | 1 / 115 (0.87%) | 0 / 106 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Nervous system disorders | | | |
| Cerebrovascular accident | | | |
| subjects affected / exposed | 0 / 115 (0.00%) | 1 / 106 (0.94%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemorrhagic stroke | | | |
| subjects affected / exposed | 1 / 115 (0.87%) | 0 / 106 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Ischaemic stroke | | | |
| subjects affected / exposed | 1 / 115 (0.87%) | 0 / 106 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Transient ischaemic attack | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 115 (0.00%) | 1 / 106 (0.94%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Eye disorders | | | |
| Keratitis | | | |
| subjects affected / exposed | 1 / 115 (0.87%) | 0 / 106 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal disorders | | | |
| Umbilical hernia, obstructive | | | |
| subjects affected / exposed | 0 / 115 (0.00%) | 1 / 106 (0.94%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatobiliary disorders | | | |
| Bile duct obstruction | | | |
| subjects affected / exposed | 0 / 115 (0.00%) | 1 / 106 (0.94%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin and subcutaneous tissue disorders | | | |
| Eczema nummular | | | |
| subjects affected / exposed | 1 / 115 (0.87%) | 0 / 106 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin ulcer | | | |
| subjects affected / exposed | 1 / 115 (0.87%) | 3 / 106 (2.83%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Stasis dermatitis | | | |
| subjects affected / exposed | 0 / 115 (0.00%) | 1 / 106 (0.94%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Musculoskeletal and connective tissue disorders | | | |
| Osteoarthritis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 2 / 115 (1.74%) | 0 / 106 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infections and infestations | | | |
| Erysipelas | | | |
| subjects affected / exposed | 1 / 115 (0.87%) | 1 / 106 (0.94%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

Frequency threshold for reporting non-serious adverse events: 3 %

| **Non-serious adverse events** | HP802-247 (in 802-247-09-032 trial) | Vehicle (in 802-247-09-032 trial) | |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 53 / 115 (46.09%) | 56 / 106 (52.83%) | |
| Injury, poisoning and procedural complications | | | |
| Excoriation | | | |
| subjects affected / exposed | 4 / 115 (3.48%) | 1 / 106 (0.94%) | |
| occurrences (all) | 4 | 1 | |
| Vascular disorders | | | |
| Hypertension | | | |
| subjects affected / exposed | 5 / 115 (4.35%) | 3 / 106 (2.83%) | |
| occurrences (all) | 6 | 3 | |
| Skin and subcutaneous tissue disorders | | | |
| Dermatitis | | | |
| subjects affected / exposed | 4 / 115 (3.48%) | 3 / 106 (2.83%) | |
| occurrences (all) | 4 | 4 | |
| Eczema | | | |
| subjects affected / exposed | 4 / 115 (3.48%) | 5 / 106 (4.72%) | |
| occurrences (all) | 4 | 5 | |
| Pruritus | | | |
| subjects affected / exposed | 4 / 115 (3.48%) | 2 / 106 (1.89%) | |
| occurrences (all) | 4 | 2 | |
| Skin ulcer | | | |
| subjects affected / exposed | 25 / 115 (21.74%) | 22 / 106 (20.75%) | |
| occurrences (all) | 40 | 47 | |
| Venous ulcer pain | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 115 (0.87%) | 4 / 106 (3.77%) | |
| occurrences (all) | 1 | 4 | |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 4 / 115 (3.48%) | 1 / 106 (0.94%) | |
| occurrences (all) | 4 | 1 | |
| Pain in extremity | | | |
| subjects affected / exposed | 0 / 115 (0.00%) | 4 / 106 (3.77%) | |
| occurrences (all) | 0 | 4 | |
| Infections and infestations | | | |
| Infected skin ulcer | | | |
| subjects affected / exposed | 2 / 115 (1.74%) | 5 / 106 (4.72%) | |
| occurrences (all) | 2 | 6 | |
| Urinary tract infection | | | |
| subjects affected / exposed | 1 / 115 (0.87%) | 5 / 106 (4.72%) | |
| occurrences (all) | 1 | 5 | |

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|---|---|
| 29 July 2013 | The amendment prescribed procedures for the handling of missing and incomplete data. |

Notes:

### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported