



Clinical trial results:

Open, Blindly Evaluated, Prospective, Controlled, Randomized, Multicenter Phase III Clinical Trial to Compare Intra-individually the Efficacy and Tolerance of Oleogel-S10 versus Standard of Care in Accelerating the Wound Healing of Split-Thickness Skin Graft Donor Sites

Summary

| | |
|--------------------------|-------------------|
| EudraCT number | 2012-003390-26 |
| Trial protocol | LV GR ES |
| Global end of trial date | 25 September 2013 |

Results information

| | |
|--------------------------------|--------------|
| Result version number | v1 (current) |
| This version publication date | 29 July 2016 |
| First version publication date | 29 July 2016 |

Trial information

Trial identification

| | |
|-----------------------|--------|
| Sponsor protocol code | BSG-12 |
|-----------------------|--------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT01657305 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|----------------------------------------------------------------------|
| Sponsor organisation name | Birken AG |
| Sponsor organisation address | Streiflingsweg 11, Niefern-Oeschelbronn, Germany, 75223 |
| Public contact | Pharmaceutical Development, Birken AG, +49 723397490, info@birken.eu |
| Scientific contact | Pharmaceutical Development, Birken AG, +49 723397490, info@birken.eu |

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 | 15 April 2014 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 25 September 2013 |
| Global end of trial reached? | Yes |
| Global end of trial date | 25 September 2013 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

To compare intra-individually the efficacy and tolerability of Oleogel-S10 versus non-adhesive wound dressing alone in accelerating the wound healing of Split-Thickness Skin Graft Donor Sites (STSG).

Protection of trial subjects:

The study was conducted in compliance with the study protocol, ethical principles originating in or derived from the Declaration of Helsinki, ethics committee informed consent regulations, and International Council on Harmonisation (ICH) Good Clinical Practice (GCP) guidelines. In addition, all national and local regulatory requirements were followed. Insurance coverage for all participating subjects was guaranteed according to applicable legal requirements. Before undergoing any study-specific procedures, subjects were informed about the nature, scope, and possible consequences of the study. The investigator was responsible for obtaining a subject's written informed consent to participate in the study.

Background therapy:

Non-adhesive wound dressing.

Evidence for comparator:

Non-adhesive wound dressing represents a standard of care for patients with STSG donor sites.

| | |
|-----------------------------------------------------------|---------------|
| Actual start date of recruitment | 04 April 2013 |
| 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 | Spain: 57 |
| Country: Number of subjects enrolled | France: 11 |
| Country: Number of subjects enrolled | Greece: 14 |
| Country: Number of subjects enrolled | Latvia: 31 |
| Worldwide total number of subjects | 113 |
| EEA total number of subjects | 113 |

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) | 90 |
| From 65 to 84 years | 17 |
| 85 years and over | 6 |

Subject disposition

Recruitment

Recruitment details:

Study participants were enrolled from 04-Apr-2013 to 26-Aug-2013 at 14 clinical centres in 4 countries: Spain (6 centres), Greece (3 centres), Latvia (2 centres), France (3 centres).

Pre-assignment

Screening details:

During screening the following was performed: informed consent, demographics, medical history, prior medication, and pregnancy test. On day of surgery the inclusion/exclusion criteria were checked. 113 subjects were screened and enrolled, but only 112 subjects were treated since the STSG surgery was cancelled for one subject.

Pre-assignment period milestones

| | |
|------------------------------|-----|
| Number of subjects started | 113 |
| Number of subjects completed | 112 |

Pre-assignment subject non-completion reasons

| | |
|----------------------------|-----------------|
| Reason: Number of subjects | No treatment: 1 |
|----------------------------|-----------------|

Period 1

| | |
|------------------------------|-----------------------------------|
| Period 1 title | Treatment period (overall period) |
| Is this the baseline period? | Yes |
| Allocation method | Randomised - controlled |
| Blinding used | Single blind |
| Roles blinded | Assessor ^[1] |

Blinding implementation details:

Treatments were intra-individually compared. The STSG donor site was divided into two areas of equal size. Since the distance of the wounds from the centre of the body might influence the wound healing process, the wound halves were randomly assigned to treatment by a temper-proof method. Treatment was open to study subjects and investigators, but assessment of efficacy was primarily based on blinded photo evaluation. Special care was taken to ensure blinding, i.e. all markings were removed.

Arms

| | |
|------------------------------|----|
| Are arms mutually exclusive? | No |
|------------------------------|----|

| | |
|------------------|-------------|
| Arm title | Oleogel-S10 |
|------------------|-------------|

Arm description:

One half of the study wound was treated with Oleogel-S10 plus non-adhesive dressing.

| | |
|----------------------------------------|--------------|
| Arm type | Experimental |
| Investigational medicinal product name | Oleogel-S10 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Ointment |
| Routes of administration | Topical use |

Dosage and administration details:

About 1 cm Oleogel-S10 ointment (approximately 100 mg) per cm² (i.e. approximately 1 mm thick) was applied at every wound dressing change (every 3 to 4 days) to one half of the STSG donor site by applying it onto the wound-facing side of the wound dressing.

| | |
|------------------|------------------|
| Arm title | Standard of care |
|------------------|------------------|

Arm description:

One half of the study wound was treated according to standard of care by applying a non-adhesive dressing.

| | |
|----------|----------------------|
| Arm type | In-active comparator |
|----------|----------------------|

| | |
|----------------------------------------|-----------------------|
| Investigational medicinal product name | Non-adhesive dressing |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Cutaneous patch |
| Routes of administration | Topical use |

Dosage and administration details:

The dressing was changed every 3 to 4 days.

Notes:

[1] - The roles blinded appear inconsistent with a simple blinded trial.

Justification: Treatment was open to study subjects and investigators, but assessment of efficacy was performed by assessors based on blinded photo evaluation.

| Number of subjects in period 1 | Oleogel-S10 | Standard of care |
|------------------------------------------|-------------|------------------|
| Started | 112 | 112 |
| Completed | 92 | 92 |
| Not completed | 20 | 20 |
| Adverse events or other safety reasons | 5 | 5 |
| Other | 2 | 2 |
| No full wound closing achieved at Day 28 | 13 | 13 |

Baseline characteristics

Reporting groups^[1]

| | |
|-----------------------|------------------|
| Reporting group title | Treatment period |
|-----------------------|------------------|

Reporting group description:

112 subjects treated had 224 wound halves that were compared.

Notes:

[1] - The number of subjects reported to be in the baseline period is not equal to the worldwide number of subjects enrolled in the trial. It is expected that these numbers will be the same.

Justification: 112 patients were randomised and received study treatment.

| Reporting group values | Treatment period | Total | |
|-------------------------------------------------------|------------------|-------|--|
| Number of subjects | 112 | 112 | |
| Age categorical | | | |
| 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) | 89 | 89 | |
| From 65-84 years | 17 | 17 | |
| 85 years and over | 6 | 6 | |
| Age continuous | | | |
| Units: years | | | |
| median | 49 | | |
| full range (min-max) | 19 to 90 | - | |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 39 | 39 | |
| Male | 73 | 73 | |

End points

End points reporting groups

| | |
|--------------------------------------------------------------------------------------------------------------------------------------------|------------------|
| Reporting group title | Oleogel-S10 |
| Reporting group description: One half of the study wound was treated with Oleogel-S10 plus non-adhesive dressing. | |
| Reporting group title | Standard of care |
| Reporting group description: One half of the study wound was treated according to standard of care by applying a non-adhesive dressing. | |

Primary: Intra-individual difference in time to wound closure

| | |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------|
| End point title | Intra-individual difference in time to wound closure |
| End point description: The primary endpoint of this study was the intra-individual difference in time to wound closure (defined as at least 95% epithelialization) between wound halves either treated with Oleogel-S10 and non-adhesive wound dressing or treated with non-adhesive wound dressing alone, based on blinded photo evaluation by three independent, blinded experts. | |
| End point type | Primary |
| End point timeframe: Within 28 days after start of treatment (Day 0 - Day 28). Photos were acquired at every wound dressing change every 3 to 4 days. | |

| End point values | Oleogel-S10 | Standard of care | | |
|-------------------------------------------|---------------------|------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 110 | 110 | | |
| Units: day | | | | |
| arithmetic mean (confidence interval 95%) | -0.8 (-1.5 to -0.1) | 0 (0 to 0) | | |

Statistical analyses

| | |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|
| Statistical analysis title | Primary analysis |
| Statistical analysis description: The test was performed as a two-sided paired t-test at a significance level of 5% for the null-hypothesis of no difference $\delta = 0$ against the hypotheses $\delta \neq 0$: $H_0: \delta = 0$; $H_1: \delta \neq 0$; | |
| Comparison groups | Oleogel-S10 v Standard of care |
| Number of subjects included in analysis | 220 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[1] |
| P-value | = 0.0232 ^[2] |
| Method | Two-sided paired t-test |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -0.8 |

| | |
|----------------------|--------------------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -1.5 |
| upper limit | -0.1 |
| Variability estimate | Standard deviation |
| Dispersion value | 3.6 |

Notes:

[1] - Difference in time to wound closure was calculated by comparing wound closure times of corresponding wound halves per patient followed by calculation of the mean of the expert-specific differences for each patient. The primary endpoint was then derived from the mean values for all subjects. If wound closure was not observed in a wound half (2 subjects), specific assumptions were made to calculate the difference e.g. wound closure later than the last photo, or intra-individual difference is 0.

[2] - The p-value indicated above is valid for the intra-individual comparison of time to wound closure between the 2 wound halves for the Intention-To-Treat analysis set (110 subjects).

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events were recorded from start of study treatment to completion of study treatment.

| | |
|-----------------|----------------|
| Assessment type | Non-systematic |
|-----------------|----------------|

Dictionary used

| | |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

| | |
|--------------------|------|
| Dictionary version | 16.0 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|---------------------|
| Reporting group title | Safety analysis set |
|-----------------------|---------------------|

Reporting group description:

The safety analysis set (SAF) includes all patients who have been treated at least once, i.e. who received any dose of Oleogel-S10 or non-adhesive wound dressing. If the application of any treatment is not certain, the patient was included in the SAF. Within the SAF, the wound halves were analyzed 'as treated'.

| Serious adverse events | Safety analysis set | | |
|---------------------------------------------------|---------------------|--|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 5 / 112 (4.46%) | | |
| number of deaths (all causes) | 0 | | |
| number of deaths resulting from adverse events | 0 | | |
| Injury, poisoning and procedural complications | | | |
| Postoperative wound complication | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 1 / 112 (0.89%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Bronchospasm | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 1 / 112 (0.89%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Psychiatric disorders | | | |
| Mania | | | |
| alternative assessment type: Systematic | | | |

| | | | |
|-------------------------------------------------|-----------------|--|--|
| subjects affected / exposed | 1 / 112 (0.89%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Infections and infestations | | | |
| Bacteraemia | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 1 / 112 (0.89%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Sepsis | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 1 / 112 (0.89%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Wound infection | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 1 / 112 (0.89%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

Frequency threshold for reporting non-serious adverse events: 0 %

| | | | |
|-------------------------------------------------------|---------------------|--|--|
| Non-serious adverse events | Safety analysis set | | |
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 60 / 112 (53.57%) | | |
| Vascular disorders | | | |
| Haematoma | | | |
| subjects affected / exposed | 1 / 112 (0.89%) | | |
| occurrences (all) | 1 | | |
| Hypertension | | | |
| subjects affected / exposed | 4 / 112 (3.57%) | | |
| occurrences (all) | 4 | | |
| Hypotension | | | |

| | | | |
|------------------------------------------------------|-----------------|--|--|
| subjects affected / exposed | 2 / 112 (1.79%) | | |
| occurrences (all) | 2 | | |
| Lymphoedema | | | |
| subjects affected / exposed | 1 / 112 (0.89%) | | |
| occurrences (all) | 1 | | |
| Thrombophlebitis superficial | | | |
| subjects affected / exposed | 1 / 112 (0.89%) | | |
| occurrences (all) | 1 | | |
| Surgical and medical procedures | | | |
| Removal of internal fixation | | | |
| subjects affected / exposed | 1 / 112 (0.89%) | | |
| occurrences (all) | 1 | | |
| General disorders and administration site conditions | | | |
| Chills | | | |
| subjects affected / exposed | 2 / 112 (1.79%) | | |
| occurrences (all) | 3 | | |
| Feeling of body temperature change | | | |
| subjects affected / exposed | 1 / 112 (0.89%) | | |
| occurrences (all) | 1 | | |
| Infusion site extravasation | | | |
| subjects affected / exposed | 4 / 112 (3.57%) | | |
| occurrences (all) | 5 | | |
| Injection site reaction | | | |
| subjects affected / exposed | 2 / 112 (1.79%) | | |
| occurrences (all) | 2 | | |
| Mucosal induration | | | |
| subjects affected / exposed | 1 / 112 (0.89%) | | |
| occurrences (all) | 1 | | |
| Oedema peripheral | | | |
| subjects affected / exposed | 3 / 112 (2.68%) | | |
| occurrences (all) | 3 | | |
| Pain | | | |
| subjects affected / exposed | 6 / 112 (5.36%) | | |
| occurrences (all) | 6 | | |
| Pyrexia | | | |

| | | | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|--|--|
| subjects affected / exposed occurrences (all) | 12 / 112 (10.71%) 13 | | |
| Immune system disorders Hypersensitivity subjects affected / exposed occurrences (all) | 1 / 112 (0.89%) 1 | | |
| Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all) Dyspnoea subjects affected / exposed occurrences (all) Productive cough subjects affected / exposed occurrences (all) | 1 / 112 (0.89%) 1 1 / 112 (0.89%) 1 1 / 112 (0.89%) 1 | | |
| Psychiatric disorders Anxiety subjects affected / exposed occurrences (all) Insomnia subjects affected / exposed occurrences (all) Tobacco withdrawal symptoms subjects affected / exposed occurrences (all) | 2 / 112 (1.79%) 2 1 / 112 (0.89%) 1 1 / 112 (0.89%) 1 | | |
| Investigations Haematocrit decreased subjects affected / exposed occurrences (all) Transaminases increased subjects affected / exposed occurrences (all) | 1 / 112 (0.89%) 1 2 / 112 (1.79%) 2 | | |
| Injury, poisoning and procedural complications Infusion related reaction | | | |

| | | | |
|------------------------------|-----------------|--|--|
| subjects affected / exposed | 1 / 112 (0.89%) | | |
| occurrences (all) | 1 | | |
| Medication error | | | |
| subjects affected / exposed | 1 / 112 (0.89%) | | |
| occurrences (all) | 1 | | |
| Post procedural complication | | | |
| subjects affected / exposed | 5 / 112 (4.46%) | | |
| occurrences (all) | 5 | | |
| Post procedural haematoma | | | |
| subjects affected / exposed | 1 / 112 (0.89%) | | |
| occurrences (all) | 1 | | |
| Procedural pain | | | |
| subjects affected / exposed | 2 / 112 (1.79%) | | |
| occurrences (all) | 2 | | |
| Wound complication | | | |
| subjects affected / exposed | 2 / 112 (1.79%) | | |
| occurrences (all) | 2 | | |
| Wound dehiscence | | | |
| subjects affected / exposed | 2 / 112 (1.79%) | | |
| occurrences (all) | 2 | | |
| Wound haematoma | | | |
| subjects affected / exposed | 3 / 112 (2.68%) | | |
| occurrences (all) | 3 | | |
| Wound haemorrhage | | | |
| subjects affected / exposed | 2 / 112 (1.79%) | | |
| occurrences (all) | 2 | | |
| Wound secretion | | | |
| subjects affected / exposed | 1 / 112 (0.89%) | | |
| occurrences (all) | 1 | | |
| Nervous system disorders | | | |
| Dizziness | | | |
| subjects affected / exposed | 1 / 112 (0.89%) | | |
| occurrences (all) | 1 | | |
| Myoclonus | | | |
| subjects affected / exposed | 1 / 112 (0.89%) | | |
| occurrences (all) | 1 | | |

| | | | |
|--------------------------------------------------------------------------|----------------------|--|--|
| Somnolence subjects affected / exposed occurrences (all) | 1 / 112 (0.89%) 1 | | |
| Syncope subjects affected / exposed occurrences (all) | 1 / 112 (0.89%) 1 | | |
| Blood and lymphatic system disorders | | | |
| Anaemia subjects affected / exposed occurrences (all) | 6 / 112 (5.36%) 6 | | |
| Leukocytosis subjects affected / exposed occurrences (all) | 2 / 112 (1.79%) 2 | | |
| Thrombocytopenia subjects affected / exposed occurrences (all) | 1 / 112 (0.89%) 1 | | |
| Eye disorders | | | |
| Conjunctivitis subjects affected / exposed occurrences (all) | 1 / 112 (0.89%) 1 | | |
| Dry eye subjects affected / exposed occurrences (all) | 1 / 112 (0.89%) 1 | | |
| Eye pruritus subjects affected / exposed occurrences (all) | 1 / 112 (0.89%) 1 | | |
| Gastrointestinal disorders | | | |
| Abdominal pain subjects affected / exposed occurrences (all) | 1 / 112 (0.89%) 1 | | |
| Abdominal pain upper subjects affected / exposed occurrences (all) | 1 / 112 (0.89%) 1 | | |
| Constipation subjects affected / exposed occurrences (all) | 8 / 112 (7.14%) 8 | | |
| Diarrhoea | | | |

| | | | |
|----------------------------------------|------------------|--|--|
| subjects affected / exposed | 1 / 112 (0.89%) | | |
| occurrences (all) | 1 | | |
| Gastrooesophageal reflux disease | | | |
| subjects affected / exposed | 1 / 112 (0.89%) | | |
| occurrences (all) | 1 | | |
| Nausea | | | |
| subjects affected / exposed | 3 / 112 (2.68%) | | |
| occurrences (all) | 3 | | |
| Vomiting | | | |
| subjects affected / exposed | 3 / 112 (2.68%) | | |
| occurrences (all) | 3 | | |
| Skin and subcutaneous tissue disorders | | | |
| Dermatitis | | | |
| subjects affected / exposed | 1 / 112 (0.89%) | | |
| occurrences (all) | 1 | | |
| Ecchymosis | | | |
| subjects affected / exposed | 1 / 112 (0.89%) | | |
| occurrences (all) | 1 | | |
| Excessive granulation tissue | | | |
| subjects affected / exposed | 3 / 112 (2.68%) | | |
| occurrences (all) | 3 | | |
| Pain of skin | | | |
| subjects affected / exposed | 10 / 112 (8.93%) | | |
| occurrences (all) | 10 | | |
| Pruritus | | | |
| subjects affected / exposed | 9 / 112 (8.04%) | | |
| occurrences (all) | 9 | | |
| Skin burning sensation | | | |
| subjects affected / exposed | 1 / 112 (0.89%) | | |
| occurrences (all) | 1 | | |
| Urticaria | | | |
| subjects affected / exposed | 1 / 112 (0.89%) | | |
| occurrences (all) | 1 | | |
| Renal and urinary disorders | | | |
| Bladder dilatation | | | |

| | | | |
|------------------------------------|-----------------|--|--|
| subjects affected / exposed | 1 / 112 (0.89%) | | |
| occurrences (all) | 1 | | |
| Cystitis noninfective | | | |
| subjects affected / exposed | 1 / 112 (0.89%) | | |
| occurrences (all) | 1 | | |
| Pollakiuria | | | |
| subjects affected / exposed | 1 / 112 (0.89%) | | |
| occurrences (all) | 1 | | |
| Urinary retention | | | |
| subjects affected / exposed | 1 / 112 (0.89%) | | |
| occurrences (all) | 1 | | |
| Infections and infestations | | | |
| Skin infection | | | |
| subjects affected / exposed | 9 / 112 (8.04%) | | |
| occurrences (all) | 9 | | |
| Urinary tract infection | | | |
| subjects affected / exposed | 2 / 112 (1.79%) | | |
| occurrences (all) | 2 | | |
| Wound infection | | | |
| subjects affected / exposed | 3 / 112 (2.68%) | | |
| occurrences (all) | 3 | | |
| Metabolism and nutrition disorders | | | |
| Hyperglycaemia | | | |
| subjects affected / exposed | 2 / 112 (1.79%) | | |
| occurrences (all) | 2 | | |
| Hyperkalaemia | | | |
| subjects affected / exposed | 1 / 112 (0.89%) | | |
| occurrences (all) | 1 | | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 29 January 2013 | <p>Main changes were:</p> <ul style="list-style-type: none">- In the secondary endpoint 'Percentage of wound epithelialisation at different time points as assessed by....', 'the investigator' was changed to 'study team member during wound dressing change'.- 'Second or third' day was changed to 'third or fourth' day for the interval of dressing change.- The number of sites was increased from 13 to 15.- In the inclusion criterion no. 2 the size of the wound area was reduced from 20 cm² to 15 cm².- In inclusion criterion no. 5, the phrase 'who are in the period between menarche and menopause' was added to women of childbearing potential.- 'Sexually active, non-vasectomized men must use a barrier method (condoms) during the treatment phase of this clinical trial' was added to inclusion criterion no. 5. |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported