Clinical Study Synopsis

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The study listed may include approved and non-approved formulations or treatment regimens. Data may differ from published or presented data and are a reflection of the limited information provided here. The results from a single trial need to be considered in the context of the totality of the available clinical research results for a drug. The results from a single study may not reflect the overall results for a drug.

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## Clinical Trial Results Synopsis

### Study Design Description

<table>
<thead>
<tr>
<th><strong>Study Sponsor</strong></th>
<th>Bayer Innovation GmbH</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Study Number</strong></td>
<td>SGF271-01 NCT00998673</td>
</tr>
<tr>
<td><strong>Study Phase</strong></td>
<td>II</td>
</tr>
<tr>
<td><strong>Official Study Title</strong></td>
<td>Randomized standard-of-care-controlled trial of a silica gel fiber (SGF) wound dressing in the treatment of chronic venous leg ulcers</td>
</tr>
<tr>
<td><strong>Therapeutic Area</strong></td>
<td>chronic venous wounds</td>
</tr>
</tbody>
</table>

### Test Product

<table>
<thead>
<tr>
<th><strong>Name of Test Product</strong></th>
<th>Silica Gel Fibre</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Name of Active Ingredient</strong></td>
<td>Silica</td>
</tr>
<tr>
<td><strong>Dose and Mode of Administration</strong></td>
<td>topical, cut and applied according to wound size</td>
</tr>
</tbody>
</table>

### Reference Therapy/Placebo

<table>
<thead>
<tr>
<th><strong>Reference Therapy</strong></th>
<th>Standard-of-Care</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dose and Mode of Administration</strong></td>
<td>topical</td>
</tr>
<tr>
<td><strong>Duration of Treatment</strong></td>
<td>12 weeks</td>
</tr>
</tbody>
</table>

### Studied period

<table>
<thead>
<tr>
<th><strong>Date of first subjects’ first visit</strong></th>
<th>21 APR 2009</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Date of last subjects’ last visit</strong></td>
<td>17 JUN 2011</td>
</tr>
</tbody>
</table>

### Premature Study Suspension / Termination

Study terminated prematurely due to slow recruitment

### Substantial Study Protocol Amendments

None

### Study Centre(s)

13 active investigational sites
### Methodology:

This was an open, randomized, standard-of-care-controlled, multi-center trial.  
Prior to the core investigation, an open, non-randomized run-in phase was conducted to gain experience in the application of SGF wound dressing in small number of subjects. In the run-in phase, all subjects received SGF wound dressing.  
In the core study, eligible subjects were randomized in a 1:1 ratio to receive either SGF wound dressing in addition to standard treatment (target ulcer only) or standard of care (S-o-C) treatment alone. The subjects were treated until complete healing of target ulcer or for a maximum of 12 weeks, followed by a 12-week follow-up period. Treatment could be prolonged to 24 weeks followed by a 4-week safety follow-up. Subjects in the S-o-C group were allowed to switch to SGF treatment after Week 12.

### Indication/ 
Main Inclusion Criteria:

1. Adult men and women aged 18 years.  
2. At least one chronic venous leg ulcer fulfilling all of the following criteria:
   - Size: > 5 cm² and < 40 cm² (measured by Visitrak® wound measurement system).  
   - Duration: > 3 months and < 5 years.  
   - Location: Between and including knee and ankle.  
   - Depth: Involving dermis, with no exposed muscle, tendon or bone.  
   - Characterized by a viable wound bed with granulation tissue.  
   - "Venous etiology" of the ulcer proven by duplex or Doppler sonography and by ankle/brachial arterial Doppler pressure index > 0.8 (exclusion criterion for peripheral arterial disease) and < 1.3 (exclusion criterion for medial sclerosis), or by laser Doppler value > 40.  
3. Treatment with active wound care agents paused for 14 days before start of study treatment.

### Study Objectives:

**Primary:**
The primary performance variable was the time to healing of the target ulcer up to the end of the 12-week treatment period.

**Secondary:**
- the time to healing of the target ulcer up to the end of the 12-week follow-up period (for subjects who continued treatment after Week 12)  
- incidence of complete wound healing of the target ulcer at different time points  
- rate of recurrence of wound at the end of the 12-week follow-up period  
- size of target ulcer at different time points (absolute size and change)  
- pain due to venous leg ulcer between dressing changes  
- pain experienced during dressing changes  
- quality of life assessment
| Evaluation Criteria: | **Efficacy (Primary):**
| | time to healing of the target ulcer up to the end of the 12-week treatment period.
| | **Efficacy (Secondary):**
| | • the time to healing of the target ulcer up to the end of the 12-week follow-up period (for subjects who continued treatment after Week 12)
| | • incidence of complete wound healing of the target ulcer at different time points
| | • rate of recurrence of wound at the end of the 12-week follow-up period
| | • size of target ulcer at different time points (absolute size and change)
| | • pain due to venous leg ulcer between dressing changes
| | • pain experienced during dressing changes
| | • quality of life assessment
| | • global assessment of dressing performance
| | **Safety:**
| | • adverse events and adverse device effects (safety)
| Statistical Methods: | **Efficacy (Primary):**
| | two-sided log-rank test (ITT data, core study)
| | **Efficacy (Secondary):**
| | sample statistics, frequency tables and exploratory tests as appropriate (separately for core study and run-in phase; additionally for pooled performance data of all subjects treated with SGF in the core study and the run-in phase).
| | **Safety:**
| | Summary tables of AE/SAE
| Number of Subjects: | Number of subjects planned to be enrolled:
| | run-in phase: 10-15
| | core study: 250
| | Number of subjects enrolled and analyzed:
| | run-in phase: 13
| | core study: 121


Study Results

Results Summary — Subject Disposition and Baseline

Table 8.2.1-3: Demographic data / core study

<table>
<thead>
<tr>
<th>ITT SGF (N = 60)</th>
<th>ITT S-o-C (N = 60)</th>
<th>PP SGF (N = 48)</th>
<th>PP S-o-C (N = 54)</th>
</tr>
</thead>
<tbody>
<tr>
<td>N  %</td>
<td>N  %</td>
<td>N  %</td>
<td>N  %</td>
</tr>
<tr>
<td>Gender: Female</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>32  53.3</td>
<td>30  50.0</td>
<td>23  47.9</td>
<td>28  51.9</td>
</tr>
<tr>
<td>Male</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>28  46.7</td>
<td>30  50.0</td>
<td>25  52.1</td>
<td>26  48.1</td>
</tr>
<tr>
<td>Age [years]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>65.5  13.3</td>
<td>70.1  13.8</td>
<td>65.0  13.5</td>
<td>70.7  13.8</td>
</tr>
<tr>
<td>BMI [kg/m2]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>31.3  6.8**</td>
<td>30.9  6.8*</td>
<td>31.8  7.0**</td>
<td>30.6  6.8*</td>
</tr>
</tbody>
</table>

*: 1 missing value; **: 2 missing values; SD: standard deviation

One patient was removed from the ITT population in the SGF group as he did not receive treatment.

Results Summary — Efficacy

Complete healing by Week 12 was documented for 10 subjects in the SGF group and for 16 subjects in the S-o-C group (ITT, all subjects); complete healing by Week 24 was documented for 15 subjects in the SGF group and 21 in the S-o-C group. (Among the latter were 2 subjects who had been switched to SGF after Week 12.) Recurrence of an ulcer already healed occurred in 1 subject per group. The above performance results were confirmed by the results of analyses based on PP data.

Results Summary — Safety

Device (wound dressing) related AEs (none of them serious) were reported for 14 subjects in the SGF group, 18 subjects in the S-o-C group and 4 subjects switched to SGF. Device related AEs (MedDRA preferred terms) that occurred in more than 2 subjects in total are listed below. There were no potential adverse device effects or AEs in users or third parties reported.

Conclusion(s)

Both treatments were safe and well tolerated.

However, the expected benefit of additional treatment of chronic venous leg ulcers with SGF wound dressing over standard-of-care treatment with respect to the time to healing within the 12-week treatment period could not be demonstrated.

Publication(s): none

Date Created or Date Last Updated: 24 May 2012