Efficacy of AutoloGel Therapy to Usual and Customary Care in Wagner gd 1 and 2 Diabetic Foot Ulcers.

The purpose of this study is to determine if AutoloGel platelet rich plasma used on non healing diabetic foot ulcers Wagner gd. 1 and 2 is more effective than the usual and customary care.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
<th>Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetic Foot Ulcer</td>
<td>Device: AutoloGel</td>
<td>Phase 4</td>
</tr>
<tr>
<td></td>
<td>Other: Usual and Customary Care</td>
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</tbody>
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Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Efficacy Study
Intervention Model: Parallel Assignment
Masking: Single Blind (Outcomes Assessor)
Primary Purpose: Treatment

Official Title: A Multi-Center, Prospective, Clinical Trial Comparing the Efficacy of AutoloGel Therapy to Usual and Customary Care in Wagner 1 and 2 Diabetic Foot Ulcers

Resource links provided by NLM:

MedlinePlus related topics: Diabetic Foot, Foot Health

U.S. FDA Resources

Further study details as provided by Cytomedix:

Primary Outcome Measures:
- Compare time to heal in Wagner 1 and 2 diabetic foot ulcers at 12 weeks treated with AutoloGel versus usual and customary care
  [ Time Frame: 12 weeks ] [ Designated as safety issue: No ]
- Complete wound closure is defined as skin re-epithelialization without drainage or dressing requirements confirmed at consecutive study visits 2 weeks apart. Initial diagnosis of healing by unblinding Principal Investigator will be confirmed by an independent blinded observer using digital photography, planimetry data and wound measurements

Secondary Outcome Measures:
- Assess wound healing trajectory and change in Chronic Wound quality of Life W-QOL scores: and to assess the comparative safety of
AutoloGel and usual and customary care [Time Frame: 13 weeks] [Designated as safety issue: Yes]

QOL tool administered prior to and at the end of treatment to document the impact of the wound on the subject's life and whether treatment interventions helped a return to improved functioning.

- Number of patients with adverse events as a measure of tolerability [Time Frame: 12 weeks] [Designated as safety issue: Yes]

  Frequency and severity of adverse events

Estimated Enrollment: 280
Study Start Date: April 2013
Estimated Study Completion Date: January 2015
Estimated Primary Completion Date: January 2015 (Final data collection date for primary outcome measure)

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<tr>
<th>Arms</th>
<th>Assigned Interventions</th>
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| Active Comparator: AutoloGel| Device: AutoloGel
| AutoloGel treatment         | Treatment with Autologel and standard of care twice a week for the first two weeks and once a week thereafter
|                             | Other Name: Autologel System                                                          |
| Usual and Customary Care    | Other: Usual and Customary Care                                                       |
| Standard of care            | Standard of care treatment twice weekly for 2 weeks then weekly                        |
|                             | Other Name: Standard of care clinically indicated                                     |

Detailed Description:
Autologel is a platelet-rich plasma gel used in the treatment of no-healing chronic wounds. Prospective observational studies of the effectiveness of Autologel have demonstrated promising results in regard to the healing of diabetic foot ulcers including severe Wagner grade 3 and 4 ulcers. The aim of the current trial is to compare the efficacy, measured as wound healing in a single-blind (assessor) randomized controlled trial, of usual and customary care with and without Autologel in treating Wagner 1 and 2 diabetic foot ulcers.

Eligibility

Ages Eligible for Study: 18 Years and older (Adult, Senior)

Genders Eligible for Study: Both

Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:
1. Medicare eligible
2. ≥18 years of age
3. Type I or II diabetes requiring medical treatment as determined by the physician
4. The largest non-healing wound, if multiple wounds are present, or the single wound to be treated (index ulcer) is a Wagner 1 or 2 Diabetic Foot Ulcer (DFU; see Appendix 9 for Wagner Classification) that is located on the plantar, medial, or lateral aspect of the foot (including all toe surfaces but not on the heel). Subjects who have heel ulcers may be included if another, eligible wound is the index ulcer
5. For subjects with potentially multiple eligible DFUs, the largest ulcer will be selected. There must be at least 4 cm between the index ulcer and other ulcers; if all ulcers are closer than 4 cm, the subject should not be enrolled (screen failure)
6. Debrided ulcer size between 0.5 cm2 and 20 cm2
7. Demonstrated adequate offloading regimen
8. Duration ≥ 1 month at first visit (screening period)
9. Subject must be willing to comply with the Protocol, which will be assessed by enrolling clinician.

Exclusion Criteria:
1. Subjects known to be sensitive to AutoloGel components (calcium chloride, thrombin, ascorbic acid) and/or materials of bovine origin
2. Wagner 3, 4, or 5 DFU (see Appendix 9 for Wagner Classification) Page 15 of 58
3. Any clinically infected index ulcer that is apparent on Day 0. The presence of infection is defined by ≥ 2 classic findings of inflammation (erythema, warmth, tenderness, pain, or induration) or purulent secretions (Lipsky, 2012, or see Appendix 4)
4. Presence of another wound that is concurrently treated and might interfere with index wound
5. Ulcer not of DFU pathophysiology (e.g., venous, vasculitic, radiation, rheumatoid, collagen vascular disease, pressure, or arterial etiology)
6. Presence of underlying osteomyelitis, or if osteomyelitis is suspected
1. Received systemic corticosteroids or immunosuppressive agents, hyperbaric oxygen therapy (HBOT), electrostimulation, growth factors, or any cell or tissue-derived products for wounds during the 30 days preceding the screening visit; received radiation therapy or chemotherapy within previous 6 months.

2. Any malignancy other than non-melanoma skin cancer.

3. Ischemic ulcer defined as an ankle brachial index (ABI; handheld or Arterial Doppler) < 0.8 (note: if ABI is ≥ 1, then an skin perfusion pressure (SPP) or transcutaneous oximetry (TCOM) must be performed or the subject cannot be enrolled), TCOM < 30 mm Hg, or SPP < 30 mm Hg; toe pressure < 45 mm Hg. These measurements may be concurrent with the initial evaluation of the index ulcer or obtained within 90 days of study enrollment if done prior to that concurrence.

4. Subject has radiographic evidence consistent with diagnosis of active Charcot foot.

5. Untreated Charcot foot or DFUs associated with a treated Charcot deformity in which reconstruction or offloading has not taken place.

6. Ulcer expected to be treated with any advanced therapeutics (e.g., HBOT).

7. Ulcer area decreases by ≥ 30% during 2-week screening/run-in period.

8. Subjects who are cognitively impaired and do not have a healthcare proxy.

9. Serum albumin of less than 2.5 g/dL.

10. Plasma Platelet count of less than 100 x 109/L.

11. Hemoglobin of less than 10.5 g/dL.

12. Subject has inadequate venous access for repeated blood draw required for AutoloGel Administration.

13. Subject requires or is anticipated to require interventions directed at improvement of arterial perfusion to affected area.

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT01816672

Contacts

Contact: Catherine Van Doren, RN  cvandoren@cytomedix.com

Locations

United States, Mississippi

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Sponsors and Collaborators

Cytomedix

More Information

Responsible Party: Cytomedix
ClinicalTrials.gov Identifier: NCT01816672  History of Changes
Other Study ID Numbers: CM001
Study First Received: March 20, 2013
Last Updated: August 18, 2014
Health Authority: United States: Food and Drug Administration

Keywords provided by Cytomedix:
Wagner 1
Wagner 2
Non healing diabetic foot wound

Additional relevant MeSH terms:
Ulcer  Skin Ulcer
Diabetic Foot  Skin Diseases
Foot Ulcer  Diabetes Complications
Pathologic Processes  Diabetes Mellitus