



Prairie

EDUCATION & RESEARCH COOPERATIVE

326 North 7th Street, Suite 101, Springfield, IL 62701 • (217) 544-6464 X 66044 • Fax: (217) 522-1206

TOPICAL II

<u>Trial Sponsor:</u>	Intercytex
<u>Principal Investigator:</u>	Raghu Kolluri, MD
<u>Trial Name:</u>	A Prospective, Multi-Centre, Double Blind, Randomized, Placebo Controlled Trial to Evaluate the Safety and Efficacy of ICXP007 in a Phase III Trial With Four-Layer Therapeutic Compression, for the Treatment of Non-Infected Skin Leg Ulcers, Due to Venous-Insufficiency
<u>Purpose:</u>	The main purpose of the study is to compare treatment of non-infected venous leg ulcers using ICXP007 combined with four-layer compression bandaging, placebo combined with four-layer compression bandaging and four-layer compression bandaging alone.
<u>Phase:</u>	Phase III
<u>Study Type:</u>	Interventional
<u>Study Design:</u>	Treatment, Randomized, Double-Blind, Placebo Control, Parallel Assignment, Efficacy Study
<u>Study Arms:</u>	3
<u>Expected Enrollment:</u>	396
<u>Study Start:</u>	July 2005

Primary Outcome Measures:

- Incidence of 100% closure (epithelialized) at any time during the initial 12 weeks of the treatment period. [Time Frame: 12 weeks]

Secondary Outcome Measures:

- Overall rate of wound area reduction during treatment.
- Time to first closure.
- Incidence of closure at 16, 20, and 24 weeks.
- Incidence of reopening at up to 16, 20 and 24 weeks.
- Incidence of re-closure at 16, 20, and 24 weeks.
- Qualitative levels of wound pain.
- Percentage of Day 0 wound surface area.
- Percentage reduction in wound surface area from previous visit.



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- Percentage reduction in wound surface area from Day 0.
- Appearance of new ulcer in the target wound area post closure.

Eligibility:

Ages Eligible for Study: 18 years and above

Genders Eligible for Study: Both

Inclusion Criteria:

- Individuals who have a graft-ready venous leg ulcer of at least 3 months duration, which has not, responded to standard conventional therapy.
- Individuals who have an Ankle Brachial Pressure Index (ABPI/ABI) of greater than or equal to 0.8 measured by Doppler sonography.
- Individuals who have venous incompetency as defined by > 1.0 seconds in vein segments on standing reflux exam by duplex or an abnormal venous refill time of < 21 seconds by PPG or > 2 cc per second by APG. Duplex or PPG/APG will be used to establish venous insufficiency. Doppler will be utilized to rule out arterial disease.
- Individuals who have a target wound which is between 2 cm² to 20 cm² in area at the screening assessment.
- Individuals who are ambulatory.
- Individuals who have voluntarily signed and dated a patient IRB/EC approved Informed Consent Form (ICF).
- Individuals, who are, in the opinion of the Investigator, able to understand this study, cooperate with the study procedures and are willing to return to the clinic for all the required follow-up visits.

Exclusion Criteria:

- Individuals with a known hypersensitivity to Aprotinin or any other constituents of Tisseel VH S/DTM i.e. Fibrinogen (human), thrombin (human) and Calcium Chloride, Bovine and Porcine products.
- Individuals who have a hemoglobin or serum albumin level which is < 10 g/dL or < 2.5 g/dL respectively, or is otherwise outside the normal range and deemed clinically significant.
- Females who are pregnant, lactating, or who have not reached menopause and are not abstinent or practicing an acceptable means of birth control as determined by the Investigator for the duration of the study.
- Individuals younger than 18 years of age.
- Individuals with abnormal blood biochemistry defined as 3 times that of the upper limit of the normal range and/or any other abnormal laboratory finding considered clinically significant.
- Individuals who have exposed bone, tendon, or fascia visible around the target wound.



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- Individuals with evidence of collagen vascular diseases, such as vasculitis or rheumatoid arthritis, under active treatment.
- Individuals with evidence of cellulitis or osteomyelitis during the previous 4 weeks.
- Individuals who have a target wound which shows signs of clinical infection or who have a wound that has presence of β -hemolytic streptococcus upon culture, or the Investigator suspects may be severely infected. Individuals may be enrolled upon eradication of the β -hemolytic streptococcus infection/organism.
- Individuals who have any clinically significant medical condition that would impair wound healing as determined by the Investigator, including uncontrolled diabetes as determined by HbA1C (>12%), or immune disease.
- Individuals who are known to abuse alcohol or drugs currently, or to have psychological disorders that could affect follow-up care or treatment outcomes.
- Individuals who have chronic renal insufficiency requiring haemodialysis.
- Individuals who have received short course corticosteroids within 30 days, or oral or parenteral chronic immunosuppressants within 90 days prior to treatment.
- Individuals who have, or are suspected of having malignancy, or who have received treatment for any active malignancy, apart from non-melanomatic skin cancer, within 3 months prior to treatment.
- Individuals who have participated in a clinical study of any investigational product within 2 months prior to treatment.
- Individuals who, in the opinion of the Investigator, have an existing condition that would compromise their participation and follow-up in this study.
- Individuals previously enrolled/randomized in this clinical trial.