

Clinical Evaluation of the Safety and Effectiveness of Harvest Autologous Platelet Concentrate and Harvest Autologous Thrombin for Treatment of Lower Extremity Chronic Diabetic Ulcers

Submission date

01/09/2005

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

28/10/2005

Overall study status

Completed

☐ Statistical analysis plan

☐ Results

Last Edited

12/01/2021

Condition category

Skin and Connective Tissue Diseases

☐ Individual participant data

☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof W.A. Scherbaum

Contact details

Deutsches Diabetes-Zentrum

Auf'm Hennekamp 65

Duesseldorf

Germany

40225

+49 (0)211 3382 200

scherbaum@ddz.uni-duesseldorf.de

Additional identifiers

Protocol serial number

2004-4

Study information

Scientific Title

Clinical Evaluation of the Safety and Effectiveness of Harvest Autologous Platelet Concentrate and Harvest Autologous Thrombin for Treatment of Lower Extremity Chronic Diabetic Ulcers

Study objectives

The study will evaluate the hypothesis that treatment of a chronic diabetic wound with Autologous Platelet Concentrate and Autologous Thrombin (and their autologous growth factors) has the potential to accelerate the reepithelialization process.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Lower extremity chronic diabetic ulcer

Interventions

Treatment with autologous platelet concentrate versus standard therapy

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Percentage of cases completely healed by 12 weeks

Key secondary outcome(s)

Not provided at time of registration

Completion date

30/11/2005

Eligibility

Key inclusion criteria

1. Age >18 years
 2. Patient and/or his/her legal representative has read and signed the IRB approved Informed Consent Form before treatment
 3. Patient or caregiver are willing and able to participate in the clinical trial for the duration of the study and are able to visit the clinic weekly
 4. Patient is willing to have blood drawn weekly
 5. Patient is compliant with standard wound care regimen assessed over 3 initial observational visits each 7 days apart
 6. Patient is diabetic (on insulin or oral hypoglycemic agent) HbA1C <10
 7. Ulcer:
 - a. Ulcer present ≥ 4 weeks
 - b. Ulcer is located on lower extremity (below knee)
 - c. Ulcer extends through the dermis and into subcutaneous tissue and may involve tendon, muscle and/or bone
 - d. Ulcer size: 0.7 cm^2 to 25 cm^2
 8. Circulation status:
 - a. Minimal disease with palpable pulses or ABI >0.7
 - b. Previously revascularized at least 4 weeks prior to enrolment by bypass or endovascular therapy
 - c. Compromised circulation with ABI 0.4-0.7 in patient not deemed to be a candidate for revascularization because of prohibitive anatomic or physiologic consideration
 9. Hematological:
 - a. Hct $\geq 30\%$
 - b. Platelet count $\geq 100,000$
 10. Adequate venous access for phlebotomy
 11. Reliable access to outpatient dressing care i.e. home nursing service, family member, patient
 12. Serum Albumin >2.5 mg/dl
- (Stratification: Wagner classification stage I or II OR stage III, creatinine clearance <40 OR ≥ 40 , Ankle Brachial Index [ABI] 0.4-0.7 OR >0.7)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Total final enrolment

59

Key exclusion criteria

1. Ulcer is located in area of radiation treatment
2. Active malignancy
3. Being treated with immunosuppressant drugs
4. Patient received biological treatment(s) within 30 days
5. Active infection - if osteomyelitis has been diagnosed, patient may be enrolled only after infection has been controlled
6. Patient has a known alcohol or drug abuse
7. Patient has a non-study ulcer on the study lower extremity that is located within 2.0 cm from the study ulcer at Day 0
8. Patient has been previously diagnosed with acquired immunodeficiency syndrome (AIDS) or human immunodeficiency virus (HIV) or hepatitis
9. Patient is undergoing dialysis
10. Ankle Brachial Index <0.4
11. Ankle Brachial Index 0.4-0.7 in patient appropriate for revascularization
12. Venous stasis ulcers. Low leg ulcers in the presence of any of the following are to be excluded:
 - a. Presence of lipodermatosclerosis in the gaiter area of the calf
 - b. Presence of varicose veins
 - c. History of deep venous thrombosis in the index limb

Date of first enrolment

01/12/2004

Date of final enrolment

30/11/2005

Locations

Countries of recruitment

Germany

Study participating centre

Deutsches Diabetes-Zentrum

Duesseldorf

Germany

40225

Sponsor information

Organisation

Harvest Technologies Corp. (USA)

Funder(s)

Funder type

Industry

Funder Name

Harvest Technologies Corp.

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration