ISRCTN28965380 https://doi.org/10.1186/ISRCTN28965380

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

Registration date
28/10/2005

Last Edited
12/01/2021

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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

Study design
Randomised controlled trial

Primary study design
Interventional

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) HbAlC <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 ≥30%
b. Platelet count ≥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 appropiate 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 gaitor 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