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Development of wound healing therapies: a randomised controlled single-blind prospective pilot study for the use of autologous keratinocytes on a transfer dressing (TranCell) in the treatment of diabetic ulcers

Submission date
22/07/2005

Recruitment status
No longer recruiting

Registration date
22/07/2005

Overall study status
Completed

Last Edited
04/02/2016

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Diabetic foot ulcers are painful red sores that can develop on the feet of people with type 1 or type 2 diabetes. The aim of this study is to find out whether the rate of healing of diabetic foot ulcers can be improved using the patient's own skin cells, grown in a laboratory (cultured) and delivered on a transfer dressing.

Who can participate?
Patients aged over 18 with diabetic foot ulcers that are resistant to conventional treatment.

What does the study involve?
Participants are randomly allocated to be treated with either a dressing containing cultured skin cells (active treatment) or a placebo (dummy) dressing for 6 weeks. All participants then receive active treatments for a maximum of 12 treatments where required.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Royal Hallamshire Hospital, Sheffield, UK

When is the study starting and how long is it expected to run for?
October 2002 to September 2005

Who is funding the study?
Wellcome Trust (UK)

Who is the main contact?
Dr Simon Heller
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
068906

Study information

Scientific Title
Development of wound healing therapies: a randomised controlled single-blind prospective pilot study for the use of autologous keratinocytes on a transfer dressing (TranCell) in the treatment of diabetic ulcers

Study objectives
This is a pilot study designed to determine whether the use of tranCell in addition to standard care improves the rate of healing of uncomplicated neuropathic diabetic foot ulcers compared to standard care alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled single-blind prospective pilot study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Diabetic foot ulcer

Interventions
This will be a pilot study, undertaken in three centres. It will be randomised with control patients receiving placebo dressings for the initial, single (patient) blind phase of six weeks. The second phase will be open and all patients will receive active dressings.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
1. Rate of ulcer healing over six and 12 weeks
2. The rate of reduction will be assessed by % reduction in ulcer area and by the decline in absolute area (mm^2)
3. % ulcers healed (full epithelialisation) at six and 12 weeks
4. % healed ulcers that remain healed at 12 weeks

Key secondary outcome(s))
No secondary outcome measures

Completion date
30/09/2005

Eligibility

Key inclusion criteria
1. Patients with type one or type two diabetes of any age over 18 years who give written informed consent
2. The presence of one or more uncomplicated pure neuropathic foot ulcers of at least four weeks duration with a cross sectional area of 0.5 cm^2 or greater on the toes or plantar surface of the forefoot
3. If patients have more than one suitable ulcer at the time of entry into the study, the ulcer of the greatest duration will be selected as the index ulcer for the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Those who withhold, or are unable to give a written informed consent
2. Those with ischaemic toes or both foot pulses (dorsalis pedis, posterior tibial) impalpable on the affected foot
3. Those who are allergic to the antibiotics used in the culture of the cells (penicillin, streptomycin, or amphotericin)
4. Those unable to attend for dressing changes at the required frequency
5. Those who are, or might become, pregnant during the course of the study
6. Acute Charcot neuropathic osteoarthropathy
7. Those who have skin conditions which may affect healing (e.g. psoriasis) or are on treatments which may impair wound healing (such as systemic steroids or immunosuppressants)
8. Those judged not to be sufficiently compliant with recommendations concerning the off-loading and the requirements of TranCell dressing changes
9. Those in whom revascularisation or other surgical procedures to the affected limb are likely to be considered during the time course of the study
10. Clinically significant active infection (involving soft tissue or bone)
11. Significant peripheral oedema
12. Ulcers probing to bone, joint or tendon

Date of first enrolment
01/10/2002

Date of final enrolment
31/03/2005

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal Hallamshire Hospital
Sheffield
United Kingdom
S10 2JF

Sponsor information

Organisation
CellTran Ltd (UK)

Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2007		Yes	No