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Cultured keratinocytes in burn wound care

Submission date
10/06/2012

Recruitment status
No longer recruiting

Registration date
25/06/2012

Overall study status
Completed

Last Edited
06/12/2016

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol

Background and Study Aims
We are recruiting up to 10 patients with severe burns to compare two different cell based approaches to help heal their wounds in an initial study. Our aim is to compare a treatment using donor skin cells with a treatment using the patients own cells. We want to compare the rates of wound closure using these two approaches, and to demonstrate that both approaches are safe. The study findings will inform future approaches to burn wound care, and may be applicable to chronic wounds also.

Who can participate
Man and women over the age of 18 who have been injured by chemical or thermal burns may participate in the study. These patients will usually require a skin graft to help heal the burnt areas.

What does the study involve
Over a period of up to two years, patients with severe burns who require a skin graft as part of their treatment will be eligible for a cell based intervention. Patients will donate a 2x2cm skin biopsy of thickness of about 0.6mm for preparation into a treatment called ReCell. This is a cell suspension derived from the patients own skin cells. These will be sprayed onto a selected area of the burn wound. In addition, a cell suspension manufactured from an accredited donor skin cell bank (Cryospray) will be applied to a separate area of the same burn wound. These two active treatment areas will be compared with a control area which receives standard care (inert dressings). One application of cells, both autologous (patients own) and allogeneic (donor) will be applied to the burn wound, and the areas will be observed at days 2, 5-7, 10 and 16. Small punch biopsies of selected treatment areas will be taken at day 0, 2 and 5-7 to identify cells responsible for healing.

What are the possible benefits and risks of participating?
There is a possible direct benefit of taking part which is that burn areas treated with cells will show accelerated healing compared to those treated with standard care. Faster wound closure can be associated with reduction in pain, reduced risk of infection and improved aesthetic and functional outcome. There should be benefits to treating future burns patients, who have relatively few effective therapies available to them. Furthermore the findings could help treatment approaches for patients with chronic skin wounds such as diabetic ulcers or venous ulcers, which affect many thousands of people in the UK and worldwide. There is a small risk of

scarring from taking a skin biopsy for the ReCell treatment, but the biopsy is not full thickness, and the wound site will be expected to heal naturally in about 12 days. Participants will provide small biopsies of healed areas these will be taken from sites selected to provide minimum discomfort and aesthetic impact, although both considerations are minor compared to the trauma associated with the initial burn injury.

Where is the study run from?
The study is set up by Queen Mary University, London, and will take place at the St Andrews Centre for Burns and Plastic Surgery, Broomfield Hospital, Chelmsford.

When is the study starting and how long is it expected to run for?
Recruitment is expected to start in July 21012. Participants will be treated for up to 17 days but will be enrolled for a period of 24 weeks to allow long term follow up of wound closure. The study will run for up to two years.

Who is funding the study?
Funding is provided by Queen Mary University, London as part of a Technology Strategy Board (TSB) regenerative medicine award. The TSB is a UK government body tasked with fostering UK innovation in priority growth areas.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
v3 020911 revised 120412

Study information

Scientific Title
Cultured keratinocytes in burn wound care: a non-randomised study

Study objectives
Cultured allogeneic keratinocytes are capapble of accelerating wound closure at least as well as autologous keratinocyte suspensions

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Non-randomised interventional study

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Severe burns - acute

Interventions
This is an intra-patient study (each patient will act as their own control) and each patient will receive all the treatment regimes under investigation i.e. Cryopsray, ReCell and standard care.

Standard care - grafting and inert bandages.

Active group 1 - cultured allogeneic keratinocytes (Cryospray) + standard care

Active group 2 - autologous keratinocyte suspension (ReCell) + standard care

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Objective measures of wound healing via punch biopsy analysis (time course of cytokine and growth factor expression)

Secondary outcome measures
1. Time to complete wound closure (100% re-epithelialisation)
2. Aesthetic outcome of burn site via Derriford Appearance Scale and Patient and Observer Scar Assessment Scale (POSAS) at week 4, 8, 12 and 24

Overall study start date
01/07/2012

Completion date
30/06/2014

Eligibility

Key inclusion criteria
1. Patients who are 18 years old at least
2. Patient is in good general health
3. Patient is willing and able to co-operate with the protocol for the duration of the study
4. Patients with a donor graft site due to requiring a split skin graft to treat a large burn
5. Patients able to give written consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Up to 10

Key exclusion criteria
1. Patients unable to give written consent
2. Terminally ill patients
3. Pregnant women
4. Patients with skin disorders that may affect the growth of cells or subsequent wound healing e.g. patients on high concentrations of steroids, patients with psoriasis or eczema

6. Patient has a history of hypersensitivity to any components of either Cryoskin Spray (e.g. DMSO) or ReCell (trypsin)
7. Patients with eczema; genetic skin conditions; hypertrophic or keloid scars

Date of first enrolment
01/07/2012

Date of final enrolment
30/06/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Queen Mary University London
London
United Kingdom
E1 4NS

Sponsor information

Organisation
Queen Mary University London (UK)

Sponsor details
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Sponsor type
University/education

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Government

Funder Name
Technology Strategy Board Grant (UK) Project Number 130412

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration