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Project RAPID: Restorative Autologous Platelet biotherapies for Injuries & Delayed wound healing

Submission date
13/10/2013

Recruitment status
No longer recruiting

Registration date
31/10/2013

Overall study status
Completed

Last Edited
24/09/2014

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol

Background and study aims
The treatment and management of complex wounds remains a clinical challenge and poses a significant socio-economic burden. Current experience indicates that about 50% of complex wounds experience delayed or prolonged wound healing which poses a significant problem to the rehabilitation of these patients, delaying their rehabilitation programmes, their overall recovery and often impacting negatively upon their psychological well-being. Considering the dynamics of advanced wound care, doctors recognise the fact that the delicate physiological balance required for optimal wound healing may be interrupted by a number of factors, including infection, resulting in delayed or sub-optimal healing, and it is under these conditions that the use of autologous biotherapies such as autologous platelet-rich plasma (PRP) gels offer an effective treatment to stimulate wound healing and restore the intricate physiological balance of the wound healing process. The study aims to evaluate the benefits of using the patient's own (autologous) concentrated tissue growth factors, obtained by taking a small sample of the patient's own blood and processing this in a sterile blood-processing system at the bedside. A platelet-rich plasma gel will be made and applied to the wound to stimulate wound healing and tissue regeneration.

Who can participate?
Patients over the age of 18 years who have long-lasting wounds that have not healed within 4 weeks of the original injury.

What does the study involve?
Participants with wounds that have not healed within the 4-week/28-day period from the initial injury will be randomly allocated to be treated with either:
1. Standard advanced wound care
2. Autologel autologous platelet-rich plasma gel plus bovine thrombin
3. Angel autologous platelet-rich plasma gel plus autologous thrombin
At the end of the study, we will compare the wound healing times, antibiotic use and overall recovery times of the different treatment groups.

What are the possible benefits and risks of participating?
The wound healing process will be improved using the patients' own platelet-rich plasma PRP biotherapies treatments. The main risk of using the PRP biotherapy treatment is that the PRP is derived from the patients blood, and repeated blood donations may cause an iron deficiency and the related anaemia because of a low haemoglobin level. Therefore, we will follow routine safety procedures to monitor haemoglobin level before donation. Participants will receive the usual finger-prick screening test for haemoglobin levels and will need to be within the safe range to be eligible to donate.

Where is the study run from?
The study has been set up by the Burns and Trauma Centre of the University Hospitals Birmingham NHS Foundation Trust (UK).

When is the study starting and how long is it expected to run for?
It is anticipated that recruitment will start at the end of 2013. Participants will be enrolled on the study for a period of two years; however, the study will extend beyond this as we intend to look at participants health over many years to assist future studies about the management of complex wounds.

Who is funding the study?
National Institute for Health Research (NIHR) (UK).

Who is the main contact?
Professor Steven Jeffery

Contact information

Type(s)
Scientific

Contact name
Prof Steven Jeffery

Contact details
The Queen Elizabeth Hospital
Mindelsohn Way
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United Kingdom
B15 2TH

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

PR19092013

Study information

Scientific Title
Randomised controlled trial of platelet rich plasma biotherapies in the management of adult patients with recalcitrant and slow healing wounds following major trauma

Acronym
RAPID

Study objectives
The use of autologous (patient's own) platelet-rich plasma (PRP) biotherapies will improve wound healing and reduce the economic burden associated with the treatment of chronic and recalcitrant wounds.

The null hypothesis is that there will be no difference between standard wound care treatment and those patients treated with autologous PRP biotherapies.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee West Midlands - Edgbaston, 19/05/2014, ref: 14/WM/0114
The Queen Elizabeth II Hospital, approval pending
University Hospitals Birmingham Hospitals Trust Ethics Committee, approval pending

Study design
Two-year open randomised group multi-site trial

Primary study design
Interventional

Secondary study design
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
Advanced and complex wound care

Interventions

Randomisation of treatment will be computer generated to avoid bias. There are three treatment arms:
1. Standard Advanced Wound Care
2. Autologel autologous Platelet-Rich Plasma Gel plus Bovine thrombin until a >90% wound closure is achieved
3. Angel autologous Platelet Rich Plasma Gel plus autologous thrombin until a >90% wound closure is achieved

Total anticipated duration of the PRP treatments will be 10 weeks. However the Standard Advanced Wound Care may very well exceed this.

Follow up for all treatment will be the same and is as per the standard care pathway for complex wounds involving a multi-centre approach.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Time to 90% wound closure as measured by 3D photography. The wounds will be monitored on a weekly basis.

Secondary outcome measures
1. Quality of life using the SF-36 health survey (this is the key secondary outcome)
2. Number of treatment 'deferrals' (i.e., temporary rejections) of donors due to low haemoglobin and other factors
3. Markers of platelet concentration, leucocyte levels within the PRP Biotherapies
4. Cognitive ability (reasoning, attention and memory)
5. Levels of physical activity
6. Cost effectiveness
7. Donor attitudes, beliefs and values

The wounds will be monitored on a weekly basis using 3D photographic measurement. Secondary outcomes regarding wound infection and antibiotic usage will be monitored on a monthly basis.

Overall study start date
01/10/2013

Completion date
01/02/2017

Eligibility

Key inclusion criteria
1. Adults (male and female patients) over 18 years of age
2. Patients with slow healing wounds and patients with wounds that have not healed within 28 days of the initial injury.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

Key exclusion criteria
Patients will be excluded if they:
1. Do not consent to participation
2. Refuse to donate blood for the PRP gel treatment
3. If any blood abnormality is detected on testing prior to treatment.

Date of first enrolment
01/10/2013

Date of final enrolment
01/02/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The Queen Elizabeth Hospital
Birmingham
United Kingdom
B15 2TH

Sponsor information

Organisation
Biotherapy Services (UK)

Sponsor details
Thames Court
1 Victoria Street
Windsor
United Kingdom
SL4 1YB

Sponsor type
Industry

Website
http://www.biotherapyservices.com/

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Efficacy and Mechanism Evaluation (EME) Programme, Ref 13/55/99

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No