ISRCTN14946762 https://doi.org/10.1186/ISRCTN14946762

The use of platelet rich plasma in the treatment of acute burns

Submission date	Recruitment status	[_] Prospectively registered
09/09/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
11/09/2015	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
10/10/2023	Skin and Connective Tissue Diseases	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
In recent years, a lot of progress has been made in the treatment of burns. Many, however, still leave disfiguring scars. For particularly severe burns which are very deep, drastic treatment is often needed in which the dead tissue is removed (excision) and healthy skin from elsewhere on the body is transplanted over the top (skin graft). Platelets are blood components vital for clotting and preventing bleeding (coagulation). They contain important substances which are thought to play an important role in wound healing, as well as protecting against bacterial infections (by forming a protective barrier between the wound surface and the blood) and providing pain relief. Platelet rich plasma (PRP) is a part of the blood plasma (the liquid part of the blood) with a high platelet concentration. There have not been many studies looking at the use of PRP in the treatment of wounds, however it has been reported to have beneficial effects in a number of studies. The aim of this study is to find out whether adding PRP to skin graft sites on burn victims can help the healing process and improve the overall appearance of scars (scar quality).

Who can participate?
Adult burn victims admitted to the Dutch burn centre Beverwijk (Netherlands) in need of a skin graft.

What does the study involve?
Before going in to surgery, blood is taken from participants so that activated platelet rich plasma can be prepared. In surgery, two similar wound areas are chosen, and are randomly assigned one of two treatments. One area receives standard care only, and the other receives standard care with the additional application of the activated platelet rich plasma. Five to seven days after the surgery, the two wound areas are inspected so that the growth of new skin over the burn wound can be assessed. Patients are also asked about their level of pain, and the presence of bacteria is also measured. The scar quality is also assessed in the outpatient clinic after 3, 6 and 12 months.

What are the possible benefits and risks of participating?
Possible benefits for participants of the study may include improved healing and scar quality. There are no notable side effects of participating.

Where is the study run from?
Burn Centre Beverwijk (Netherlands)

When is the study starting and how long is it expected to run for?
January 2010 to January 2014

Who is funding the study?
1. Association of Dutch Burn Centers (Netherlands)
2. Biomet Nederland BV, Dordrecht (Netherlands)

Who is the main contact?
Dr Roos Marck

Contact information

Type(s)
Scientific

Contact name
Dr Roos Marck

Contact details
Burn Centre
Vondellaan 13
Beverwijk
Netherlands
1942 LE

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
NL28331.094.09

Study information

Scientific Title
The application of platelet rich plasma in the treatment of deep dermal burns: a randomized, double blind, intra-patient controlled study

Study objectives

This study aims to clarify the effect of autologous PRP on take rate and epithelialization rate in the treatment of deep dermal and full thickness burn wounds that require excision and skin transplantation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethical Testing Committee, Alkmaar, The Netherlands, 01/06/2010, ref: NL28331.094.09

Study design
Double-blind randomized parallel trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Burn wounds

Interventions
In patients with burn wounds, one area is treated with excision of the burn and application of a split skin graft (standard care) and in a comparable area with burn wounds, autologous platelet rich plasma is added to the standard care.

Intervention Type
Biological/Vaccine

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
-

Primary outcome measure
Take rate (percentage of the graft that appeared to be vital and showed good adherence to the wound bed) and epithelialization rate (percentage of the wound closure by either skin graft or outgrowth from graft or wound edges) of the split skin grafts of area A and B at day 5-7 post surgery, as judged by experienced burn clinicians.

Secondary outcome measures
1. Pain and itch scores of area A and B after surgery until discharge measured using Visual Analogue Thermometer (VAT) score
2. Bacterial status of area A and B before surgery and twice weekly until discharge with swabs
3. Scar quality at 3, 6 and 12 months of area A and B measured by the POSAS scar assessment scales, Dermaspectrometer (scar color and pigmentation) and Cutometer (scar elasticity)

Overall study start date
01/06/2010

Completion date
30/06/2014

Eligibility

Key inclusion criteria
1. Aged 18 years and older
2. Admitted at the Dutch burn centre in Beverwijk with a full thickness or deep dermal burn wounds with a surface area of at least 2% total body surface area (TBSA) who needed transplantation with a split skin graft

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
52

Key exclusion criteria
1. Likely problems, in the judgment of the investigators, with maintaining follow-up
2. Insufficient comprehension of the Dutch language to understand a rehabilitation program and other treatment information in the judgment of the attending physician

Date of first enrolment
03/06/2010

Date of final enrolment
01/01/2013

Locations

Countries of recruitment

Netherlands

Study participating centre
Burn Centre Beverwijk
Vondellaan 13
Beverwijk
Netherlands
1942 LE

Sponsor information

Organisation
Red Cross Hospital

Sponsor details
Vondellaan 13
Beverwijk
Netherlands
1942 LE

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00vyr7c31

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Association of Dutch Burn Centers

Funder Name
Biomet Nederland BV, Dordrecht

Results and Publications

Publication and dissemination plan

We will present these results at the upcoming European Burn Association Conference September 18th 2015 in Hannover. Furthermore we would like to submit this paper to a peer-reviewed journal in the Trauma or Burn field.

Intention to publish date

31/12/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	Substudy results	12/01/2019	10/10/2023	Yes	No