

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

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Registration date 11/09/2015	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 10/10/2023	Condition category Skin and Connective Tissue Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
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

Study type(s)

Treatment

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)

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Primary outcome(s)

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.

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

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

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