A randomized controlled trial comparing autologous platelet rich plasma versus only standard treatment for treating burn wounds

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The primary objective is to examine the effect of PRP on the time in days to complete healing.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Epidermal and dermal conditions
Study type	Interventional

Summary

ID

NL-OMON35701

Source
ToetsingOnline

Brief title
PRP in burns

Condition

- Epidermal and dermal conditions

Synonym
burns, full thickness

Research involving
Human

Sponsors and support

Primary sponsor: Rode Kruis Ziekenhuis
Source(s) of monetary or material Support: Rode Kruis Ziekenhuis

Intervention

Keyword: burns, growth factors, platelets, woundhealing

Outcome measures

Primary outcome

The main study endpoint is the effect of PRP on the time in days to complete

healing of the grafted butn wound sites.

Secondary outcome

1. Infection rate of the transplanted burn wounds in comparison with standard

treatment.

2. Pain meassured daily with a VAS scale to complete healing of the paired

grafted burn wound sites.

3. Scar assessment with the POSAS scale in comparsion with standard treatment

after 3, 6 months and one year.

Study description

Background summary

Autologous platelet rich plasma (PRP) can be collected into a highly concentrated formula. When plateletes become activated, growth factors are released and inititate the body's natural healing response.

Autologous platelet-rich plasma (PRP) contains different growth factors such as platelet-derived growth factor (PDGF)-BB, transforming growth factor (TGF)-β1, vascular endothelial growth factor (VEGF), endothelial growth factor (EGF) and fibroblast growth factor (FGF). Growth factors play a role in wound healing, wound maturation and scar formation.

In a prospective, single-blind, pilot study autologous platelet gel, hastened wound closure in acute dermal wounds. In a randomised controlled trial autologous platelet gel increased the healing rate and shortened the time to undergo reconstructive plastic surgery in acute trauma wounds. Also in chronic

non-healing wounds PRP is used. For instance two prospective randomised trials examined the use of autologous platelet-rich plasma in diabetic foot ulcers. In one trial the percentage healed wounds was higher and the time to healing was shorter in the platelet-rich plasma gel treated group. In a clinical study 14 patients with deep dermal burns were daily treated with commercially available basic fibroblastic growth factor (bFGF) and this treatment was compared with the other side which was treated with moist dressings. Significant better healing percentages were seen after two and three weeks with bFGF.

Different platelet-concentration preparation systems are now commercialy available. The Gravitational Platelet Separation System (GPS, Biomet Merck Biomaterials, Darmstadt, Germany) is a commercialy available technique for the extraction of PRP. The preparation can be performed in the operating room during the surgical procedure and takes about 30 minutes. The blood of the patient (55 cc) is centrifuged to platelet rich plasma.

Study objective

The primary objective is to examine the effect of PRP on the time in days to complete healing.

Study design

Double-blind intervention study.

Intervention

Two equal wound areas of at least 1% of every patient are treated, one wound area is treated with PRP and one wound area with only standard treatment.

Study burden and risks

Both treatments that patient can be allocated to are standard treaments. An increase in woundhealing might be expected and therefore better results in scar formation.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Adult men and women aged 18 years and older (no upper age limit)
2. A full thickness burn which needs primary or secondary transplantation
3. provision of informed consent by patient

Exclusion criteria

1.Likely problems, in the judgement of the investigators, with maintaining follow-up (e.g.patients with no fixed adress will be excluded)
2. Insufficient comprehension of the Dutch language to understand a rehabilitation program and other treatment information in the judgement of the attending physician.

Study design

Design

Study phase: 4

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2010
Enrollment:	52
Type:	Actual

Ethics review

Approved WMO Date:	01-06-2010
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL28331.094.09