The application of autologous platelet rich fibrin reduces allogeneic blood transfusions and improves wound healing in total hip arthroplasty

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hepatobiliary neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON29827

Source
ToetsingOnline

Brief title
Platelet rich fibrin in THA (total hip arthroplasty)

Condition

- Hepatobiliary neoplasms malignant and unspecified
- Joint disorders
- Bone and joint therapeutic procedures

Synonym
coxarthrosis

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: stichting FERET

Intervention

Keyword: blood, Platelet rich fibrin, total hip arthroplasty, transfusion

Outcome measures

Primary outcome

Transfusion of homologous blood products

Surgical wound healing

Secondary outcome

Patient characteristics

Surgical wound leakage

Surgical wound infection

Pain medication

Risk factors for wound healing disturbances

Red Blood Cell Mass

Surgical information

PRF application-data

Blood management-data

Study description

Background summary

Total hip arthroplasty (THA) is often associated with a considerable amount of per- and post-operative blood loss, requiring allogeneic blood product transfusions (ABPTs) (1). The risks of ABPTs have been described extensively and comprise the whole range of transfusion related as well as human error related risks (2-5). However, ABPTs in patients undergoing a THA primarily increase the risk for infections, fluid overload and increased duration of hospitalization (6,7). Increased awareness of these complications has led to a continuous search for blood conservation techniques in orthopaedic surgery (8). Most conservation techniques primarily concentrate on managing blood loss and/or trying to avoid the transfusion trigger, instead of focussing more on less surgical bleeding, improved haemostasis and wound healing.
PRF® is manufactured from a small volume of the patients own blood. Treatment with PRF® involves direct application of concentrated platelets using fibrin as a carrier and a delivery media to ensure controlled and prolonged release of platelet growth factors. The high concentration of fibrin binds and protects several growth factors from proteolytic degradation and protects the sealant from an early fibrinolysis (11). Platelet growth factors, especially PDGF, TGF-β and VEGF, have favourable effects on the augmentation of the wound healing cascade (12,13,14). The use of PRF® has shown an enhanced effect on fibroblast proliferation in vitro as well as in vivo, where other commercial fibrin sealants did not have that effect (15).
The treatment with PRF® also involves application of vital white blood cells (16). Leukocytes also participate in wound healing through production of growth factors, destruction of bacteria and foreign material and digestive removal of damaged tissue in the wound, as a function of the myeloperoxidase mechanism of the granular neutrophils. In the human body, neutrophils are believed to be the first line of defence against invading micro- organisms. After phagocytosis of microorganisms neutrophil granules fuse with the phagosome containing the microorganisms. In azurophilic granules, myeloperoxidase (MPO) is present at a high concentration.
We believe that the high concentration of vital neutrophils and monocytes containing MPO are responsible for the supposed antibacterial effect of PRF®. Research on a formulated enzyme system based on myeloperoxidase has shown a rapid kill various bacteria, such as MRSA, and antibacterial effects were better than with antibiotics. Moreover, in vivo testing on rats, showed that this system was effective in eliminating bacteria in solution and at open surgical sites (17,18,19) .
The anti-bacterial effect of the myeloperoxidase, released from the neutrophils and monocytes in the PRF® might not only benefit early outcome but even result in an
unexpected long term benefit. In this perspective antibiotic treatment has

already proven its value in THA with regard to the drastic reduction of the revision rate for a-septic loosening and deep infection (20,21). However, it is suggested that not only in the infected prosthesis but also in the majority of a-septic loosening cases, bacteria are involved that can only be identified with more sensitive techniques as PCR (polymerase chain reaction) detection. Because of its microbicidal properties the application of PRF® might affect the incidence of both deep infection as a-septic loosening related revisions.
In a recent in vitro study we investigated the microbicidal effect of platelet gel showing the kill of MSSA within 12 to 18 hours after application, in contrast with the control group.

Study objective

The primary objective of this study is to investigate whether application of PRF® will reduce postoperative wound leakage, the necessity for allogeneic blood transfusions and the incidence of wound healing disturbances in patients undergoing unilateral primary THA.
The primary endpoints of this study will be the use of allogeneic blood products and the incidence of wound healing disturbances.
Secondary objectives of this study are to investigate whether PRF® will reduce the loss of Red Blood Cell Mass (RBCM), improve primary healing of incision sites, the incidence of wound infections (superficial or deep) and the use of pain medication for pain sensations at surgical wound site.
Secondary endpoints will be:
• Difference in RBCM between pre-operative status and the 5th post- operative day.
• The course of haemoglobin (Hb) value.
• The difference in fluid administration.
• The amount and duration of wound leakage.
• The incidence of wound infections.
• Use of pain medication for surgical site pain.

Study design

This investigation is a prospective, randomized study, comparing the use of allogeneic blood products, the amount and duration of wound leakage and the incidence of wound healing disturbances in patients with primary osteoarthritis undergoing a THA. After enrolment, 50% of the patients will be treated with PRF® (PRF-group) and 50% of the patients will receive conventional treatment only (control-group).
All patients in the study will be divided into 4 subgroups; patients with cemented and non-cemented prosthesis and with or without PRF-treatment, although we don*t expect any differences in outcome with regard to our study objectives between cemented and non-cemented THA.

Intervention

Intra-operatively, after spinal anaesthesia has been administered, a volume of 120 ml of whole blood will be collected, through a peripheral line in the median cubital vein, in a special reservoir called the Preparation Unit. The Preparation Unit already contains a citrate volume for anti-coagulation. The preparation unit will be placed in the Processor Unit and after 23 minutes an autologous PRF-solution is ready to use. The concentration of platelets in Vivostat® PRF® is approximately 10 times the platelet level of the donor*s blood. The high amount of platelets is combined with a concentration of fibrin of approximately 7-10 times over baseline. The syringe containing the Vivostat® PRF® solution can than be loaded into the Applicator Unit. The PRF® is ready for application using a spray pen. The residual volume in the Preparation Unit has to be discarded and can not be infused back into the patient. The system requires no added thrombin. The PRF® solution polymerises immediately upon application by a simple pH-change at the tip of the spray pen.

Study burden and risks

Theoretically blood is at risk for bacterial contamination at the moment of drawing blood from the patient to fill the preparation unit. From the preparation process until the application of the APRF the whole process is fully automated. Therefore the risk for bacterial contamination is practically eliminated compared to conventional preparation techniques.
We don't expect any adverse effects of the application of the PRF, because it's an autologous product.

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

patients with primary ostheoarthritis who need total hip arthroplasty

Exclusion criteria

coagulation diseases, use of anticoagulant drugs, renal problems or failure, liver disease, and malignant disease

Study design

Design

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

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-03-2007

Enrollment:	152
Type:	Actual

Ethics review

Approved WMO Date:	30-11-2006
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL13507.060.06