Randomized clinical trial for Fibrin Sealant in knee surgery

Published: 05-09-2008
Last updated: 08-05-2024

• To study the effectiveness of fibrin sealant produced of single donor allogeneic plasma when used intra-operatively after total knee replacement.o Primairy endpoint: total volume of fluid in the drains at 6h post-operative.o Secondary endpoints:...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone and joint therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON31572

Source
ToetsingOnline

Brief title
Fibrin Sealant in knee surgery

Condition

- Bone and joint therapeutic procedures

Synonym
total knee replacement; knee surgery

Research involving
Human

Sponsors and support

Primary sponsor: Sanquin Bloedbank
Source(s) of monetary or material Support: Medical Device Management,Sanquin blood supply

Intervention

Keyword: Fibrin sealant, Knee, Volume of drain fluid

Outcome measures

Primary outcome

total volume of fluid in the drains at 6h post-operative.

Secondary outcome

Secondary endpoints: total volume of fluid in the drains at 24h post-operative,

amount of blood transfused, size of the knee, amount of pain and mobility

(quality of life) after surgery, length of stay in hospital, adverse events,

satisfaction with fibrin sealant as used by the physician.

Study description

Background summary

• Thermogenesis is a company that sells a machine for the production of fibrin sealant of single donor plasma, the CryoSeal Fibrin Sealant System (CS-1).
• Fibrin sealant consists of two components: cryoprecipitate and thrombin. Cryoprecipitate is the fraction of human plasma that contains concentrated coagulation factors, such as fibrinogen. Thrombin is an enzyme that facilitates the conversion of fibrinogen into fibrin, so that a clot will be formed.
• Fibrin sealant can be used in surgery to increase hemostasis in the wound after e.g. knee replacement, cosmetical surgery or partial liverresections.
• Until now, mainly autologous plasma was used to produce fibrin sealant with the CS-1. Within Sanquin there is a question whether fibrin sealant that is also effective in the patient can be produced from the allogeneic quarantaine plasma that is in stock. Therefore in this study will be studied whether allogenous single donor fibrin sealant produced using the CS-1 is effective in reducing the amount of fluid in the drains post-operative and as consequence of this can be registered as a product of Sanquin.
• Allogenous quarantain plasma is plasma derived from voluntairy unpaid donors. The plasma will be released only when two sets of tests with negative test results. The first tests are imediately after donation, the second series of tests is after 6 months when donor is tested again.

Study objective

• To study the effectiveness of fibrin sealant produced of single donor allogeneic plasma when used intra-operatively after total knee replacement.
o Primairy endpoint: total volume of fluid in the drains at 6h post-operative.
o Secondary endpoints: total volume of fluid in the drains at 24h post-operative, amount of blood transfused, size of the knee, amount of pain and mobility (quality of life) after surgery, length of stay in hospital, adverse events, satisfaction with fibrin sealant as used by the physician.

Study design

• The study is a randomized prospective clinical trial.
• Fibrin sealant treated patients will be compared with non fibrin sealant treated patients.
• Patients included undergo total knee replacement.
• During participation of the patient, only the study coordinator of the hospital and the staff of the operation room know whether a patient is treated with fibrin sealant or not.
• Nurses and patients can be informed at the end of participation of the patient (about six weeks after discharge of the hospital).

Intervention

Surgery will be performed as usual. Only just before wound closure the fibrin sealant will be spayed over the wound surface.

Study burden and risks

nihil to very low additional risks

Contacts

Public
Sanquin Bloedbank

postbus 1191
9701 BD Groningen
Nederland
Scientific
Sanquin Bloedbank

postbus 1191
9701 BD Groningen

Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

•patients who will undergo knee replacement susrgery
•Age, minimum of 18 years
•Gender, man or woman
•Admission of the patient after informed consent

Exclusion criteria

•Liver failure
•Congenital or acquired coagulation disorders
•Patients who need coumarine derivatives (acenocoumarol or fenprocoumon) < 3 days pre-operative or < 5 days post-operative

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-08-2009
Enrollment:	257
Type:	Actual

Ethics review

Approved WMO

Date:	05-09-2008
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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	NL16130.056.07