The use of Fibrin sealant In total knee Replacement Surgery Trial. A prospective randomised multicentre study.

Published: 15-09-2010
Last updated: 10-08-2024

Is the application of CryoSeal (CS) in primary total knee replacement surgery beneficial for the patient with respect to a faster track and improved postoperative rehabilitation. The beneficial effect may be due to quicker functional knee...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON38022

Source
ToetsingOnline

Brief title
FIRST study

Condition

- Joint disorders

Synonym
osteoarthritis, total knee replacement

Research involving
Human

Sponsors and support

Primary sponsor: Sanquin Bloedbank
Source(s) of monetary or material Support: Sanquin bloedbank

Intervention

Keyword: Fibrin sealant, function, knee, replacement

Outcome measures

Primary outcome

Difference in extension angel pre-operatively and 2 (and 6) weeks after surgery

Secondary outcome

Secondary endpoints: postoperative complications, VAS pain score, knee function

Flexion/Extension, Barthel score (day 3); Outpatient department scores (2

weeks, 6 weeks and 3 months, 1 year): Complications, VAS pain knee function,

KSS, KOOS, SF-12, IPQ-K and EQ5D

Study description

Background summary

Fibrin Sealant is known to have some potential benefits for intraoperative use, especially in the acceleration of the coagulation cascade. Most studies with fibrin glue are focussing on the reduction of allogeneic blood transfusion and the possibilities to reduce costs. Firstly, fibrin sealant was made from patients* blood plasma but the logistic problems made introduction in general hard. Now Sanquin has produced a CryoSeal (fibrin sealant) made of single-donor plasma which can be used during surgery. This application is already used in cardiothoracic surgery.

Study objective

Is the application of CryoSeal (CS) in primary total knee replacement surgery beneficial for the patient with respect to a faster track and improved postoperative rehabilitation. The beneficial effect may be due to quicker functional knee rehabilitation, by pain reduction, better mobilisation and improved quality of life during the early postoperative period.

Study design

Randomised controlled trial stratified by clinic.

Intervention

The intervention is the application of CryoSeal during surgery according to the standardised manner. The control group will receive standard care.

Study burden and risks

Given the origin of the CryoSeal product, i.e. donor plasma and in the absence of added bovine or chemical fibrinolysis inhibitors, no toxicity is to be expected by applying CryoSeal produced by the CS-1 (machine) / CP-3 (disposable) system, which was confirmed by pre and clinical research.

Contacts

Public
Sanquin Bloedbank

Plesmanlaan 1a
LEIDEN 2333 BZ
NL
Scientific
Sanquin Bloedbank

Plesmanlaan 1a
LEIDEN 2333 BZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- planned for elective primary total knee replacement
- older than 18 years
- ASA classification I-III

Exclusion criteria

- liver failure
- coagulation disorder
- patients with known hemophilie or von Willibrand disease
- patients with INR >2

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):	01-01-2011
Enrollment:	500
Type:	Actual

Ethics review

Approved WMO

Date:	15-09-2010
Application type:	First submission

Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	19-12-2011
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	08-02-2012
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	16-10-2012
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL32594.058.10