The use of Fibrin Sealant in total knee replacement surgery.

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Is the application of CryoSeal (CS) by primary total knee replacement surgery beneficial for the patient with respect to a faster track and improved early (2 and 6 weeks) postoperative rehabilitation as determined by improved knee extension.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24264

Bron
NTR

Verkorte titel
Cryoseal in TKR

Aandoening

TKR, Cryoseal, fibrin, rehabilitation

Ondersteuning

Primaire sponsor: Sanquin blood bank, Leiden
Overige ondersteuning: Sanquin blood bank, Leiden

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Postoperative knee function in mean extension difference with goniometric at 2 and 6 weeks (in relation to secondary endpoints), corrected for pre-operative extension.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

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.
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:

Multicenter, randomised controlled trial stratified by clinic.

Study population:

Patients aged above 18 years scheduled for primary total knee replacement because of osteoarthritis or rheumatic arthritis, meeting all the inclusion criteria and none of the exclusion criteria, are eligible for inclusion in the study.

Intervention:

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

Main study parameters/endpoints:

Primary endpoint: Postoperative knee function in mean extension difference with goniometric

at 2 and 6 weeks (in relation to secondary endpoints), corrected for pre-operative extension.

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.

Nature and extent of the burden and risks associated with participation benefit and group relatedness:

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.

Interim analysis
When a total sample size of 500 patients appeared to be reasonable (by the 2 wks standard deviations of the P.E.) a single interim analysis will be performed in the first 250 patients. Considering patients with and without drain, we compute the pre- and post-operative differences in extension angles as primary outcome. We compare the patients with and without Cryoseal in an analysis of variance adjusting for the pre-operative extension angles. We perform a one-sided test at level 0.0025. If we find a significant difference, we stop including patients. The study will also stop when both arms show significant increase in extension function when > 600 patients are needed.
If we do not find a significant difference, we will proceed to test for futility. In 250 patients, we perform a one-sided test at level 0.1 to determine if patients with Cryoseal show SMALLER post-operative difference in extension angles, compared to those without Cryoseal. If we reject this hypothesis, we stop the inclusion of patients.

Doel van het onderzoek

Is the application of CryoSeal (CS) by primary total knee replacement surgery beneficial for the patient with respect to a faster track and improved early (2 and 6 weeks) postoperative rehabilitation as determined by improved knee extension.

Onderzoeksopzet

1. Pre-operative;

2. 2 weeks;

3. 6 weeks;

4. 1 year.

Onderzoeksproduct en/of interventie

The CryoSeal (CS) experimental product consists of two components: cryoprecipitate and thrombin. Cryoprecipitate is one fraction of a single human plasma donation that contains concentrated coagulation factors, such as fibrinogen, which together with the second fraction containing an enzyme thrombin, that facilitating the conversion of fibrinogen into fibrin. Together mixed they will form a clot. This product has two main advantages compared to other current available preparations, namely a single donor-exposure compared to commercial allogeneic fibrin Sealant (FS) products, produced from pooled multiple plasma donations which also has a bovine thrombin source and secondly the controlled hemostatic conditions of the product compared to autologous FS, prepared prior to surgery or at the operation theatre and which content is dependent on its hemostatic condition of patients (age, co-morbidity Based on preliminary estimations on CS use in the literature (1), 12-15 ml CS is expected to be used per patient randomized for CS.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients who will undergo primary total knee replacement surgery for osteoarthritis or rheumatic arthritis;

2. Age, minimum of 18 years;

3. (Admission of the patient after informed consent);

4. ASA classification I-III.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Liver failure;

2. Congenital or acquired coagulation disorders;

3. Patients with known haemophilia or von Willibrand disease;

4. Patients with INR >2 (standard practice for operation).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-01-2011

Aantal proefpersonen:	500
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	09-09-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2393
NTR-old	NTR2500
Ander register	METC sanquin : P10.115
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A