Does the application of cryolijm SQ fibrin sealant, for abdominal closure after secondary DIEP flap surgery, leads to a quicker recovery with less complications? A randomized controlled study.

Published: 21-08-2012
Last updated: 07-02-2025

The aim of this study is to assess the efficacy of Cryolijm SQ (Sanquin blood supply foundation, Groningen, The Netherlands) fibrin sealant in reducing postoperative drainage at the abdominal donor site which could result in earlier drain removal,...

Ethical review	Approved WMO
Status	Completed
Health condition type	Haematological and lymphoid tissue therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON37540

Source
ToetsingOnline

Brief title
Cryolijm SQ fibrin sealant application in DIEP flap surgery

Condition

- Haematological and lymphoid tissue therapeutic procedures

Synonym
Nvt

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Abdomen, Cryolijm, Discharge, drain production

Outcome measures

Primary outcome

Days to drain removal

Secondary outcome

1. Total postoperative abdominal drain production

2. Days of hospital admission

3. Abdominal complications and side effects

4. Blood transfusions

Study description

Background summary

Deep Inferior Epigastric Perforator (DIEP) Flap surgery is a surgical technique for breast reconstruction by autologous tissue derived from the abdomen. During closure of the abdomen 2 vacuum drains are left behind which are typically removed after 5 to 7 days postoperatively. Occasionally, drain production takes a longer period of time or the patient needs blood transfusions as a consequence of prolonged drain production from the abdominal wound. Moreover, discharge with drains in situ is often not tolerated by patients and considered a possible risk factor for infections. As a consequence patients stay in the hospital until all drains are removed.
This prolonged hospital admission leads to higher costs, ineffective use of hospital beds and possibly delayed physical and psychological recovery of patients. Literature describes the use of conventional fibrin sealant to reduce drain production and chance of complications.

Study objective

The aim of this study is to assess the efficacy of Cryolijm SQ (Sanquin blood supply foundation, Groningen, The Netherlands) fibrin sealant in reducing postoperative drainage at the abdominal donor site which could result in earlier drain removal, shorter hospital admissions, fewer blood transfusions and less post operative abdominal wound complications after DIEP flap breast reconstructions.

Study design

In this randomized controlled study, all women who receive an autologous DIEP flap breast reconstruction at the department of Plastic, Reconstructive and Hand Surgery of the Erasmus MC will be eligible for this study if they meet the proper inclusion criteria. Patients will be randomized in two groups: conventional closure of the abdominal wound without the use of Cryolijm SQ fibrin sealant and closure of the abdominal wound in combination with the application of Cryolijm SQ fibrin sealant on the abdominal wound.

Intervention

Cryolijm SQ (Sanquin blood supply foundation, Groningen, The Netherlands) is an allogenic single-donor fibrin sealant produced from fresh-frozen quarantined plasma of healthy donors.

Study burden and risks

The benefits of this project may be a decrease in abdominal donor site complications and earlier discharge from the hospital which will result in reduced costs and possibly in a faster physical as well as psychological recovery.
There is no extra burden associated with participation in this study.
The procedure for each group is the same; the only difference is the application of Cryolijm SQ in one group in addition to the standard procedure.
This product is much safer concerning anaphylactic reactions and potential blood transmitted diseases compared to the normal used commercial products of fibrin sealant

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

s-Gravendijkwal 230
Rotterdam 3015 CE
NL

Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

s-Gravendijkwal 230
Rotterdam 3015 CE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Female >= 18 years old;
Scheduled to undergo an elective DIEP flap breast reconstruction;
Provided informed consent
Not meet any of the exclusion criteria.

Exclusion criteria

Female <= 17 years;
Abdominoplasty in their past history;
Medical history of Diabetes Mellitus or vascular disorders
Use of immunosuppressant or steroids.

Study design

Design

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

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	31-08-2012
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	21-08-2012
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL39515.078.12

Study results

Date completed: 10-01-2013

Summary results
Trial ended prematurely