Autologous Platelet-Leukocyte Gel Therapy during sternum closure in cardiac surgery patients at risk for post-operative infection.

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To investigate whether application of APLG will lead to reduction in: 1) sternal wound infections 2) vessel harvest site infections 3) postoperative blood loss 4) postoperative pain

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

Summary

ID

NL-OMON29722

Source
ToetsingOnline

Brief title
APICS

Condition

- Bacterial infectious disorders
- Cardiac therapeutic procedures

Synonym
mediastinitis, post-operative infection, woundinfection

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis

Source(s) of monetary or material Support: FERET foundation

Intervention

Keyword: APLG, infection, mediastinitis, platelet-leukocytegel

Outcome measures

Primary outcome

Incidence of sternal wound infections during the first 90 days after surgery

Secondary outcome

• Total amount of postoperative blood loss

• Amount of blood products given

• Incidence of non-healing wounds

• Incidence of vessel harvest site infections

• Pain sensation at sternal wound and vessel harvest site(s)

• Use of pain medication

Study description

Background summary

From literature, it is estimated that up to 9% of the cardiac surgical patients will experience a sternal wound infection during the first 90 days after surgery. In this study, patients with all-cause cardiac surgery and at least 2 risk factors for sternal wound infection will be included. It is estimated that having at least 2 riskfactors will increase the risk of infection with a factor 2-3. This risk of infection might be reduced by locally applying Autologous Platelet-Leukocyte Gel (APLG),which will be derived from the patient*s own blood. Platelets and leukocytes in the gel release growth factors that induce wound healing and prevent infection. Furthermore platelets form plugs thereby possibly reducing postoperative blood loss. APLG will also be applicated in vessel harvest sites to reduce te risk of vessel harvest sites infection.

Study objective

To investigate whether application of APLG will lead to reduction in:
1) sternal wound infections
2) vessel harvest site infections
3) postoperative blood loss
4) postoperative pain

Study design

A prospective, randomized, single blinded mono-center study

Intervention

Patients randomized to the APLG group will receive APLG in the sternal wound, and if graft material is harvested, to the harvest site wound(s) as well. From each patient approximately 20% of circulating bloodvolume will be collected at the beginning of the surgery. From this blood the APLG will be processed by one of the perfusionists. A large amount of this blood, which will remain after producing APLG, will be returned as erythrocyte concentrate at the end of the operation.

Study burden and risks

For each patient enrolled in the study, information will be collected during hospitalisation (including surgery) and during the standard post-operative control visit. Only the visit 90 days after surgery is extra, during which only information will be collected.

Theoretically blood(products) are at risk for bacterial contamination during preparation and application. Because APLG is being produced in an aseptic way during operation, the risk of infection is estimted as very low. From literature and our own experience we know that producing and application of the gel is safe.

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

indication for cardiac surgery
planned medial sternotomy
high risk for post-operative infection
signed informed consent by patient

Exclusion criteria

emergency surgery
active endocarditis
pre-exsisting infection/use of antibiotics
age beneath 18 years

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):	01-01-2007
Enrollment:	700
Type:	Actual

Ethics review

Approved WMO Date:	31-08-2006
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	NL13127.060.06