The incidence of pulmonary embolism in patients undergoing abdominal flap breast reconstructions, a prospective study.

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The primary aim of this study is to prospectively assess the incidence of pulmonary embolism in patients undergoing abdominal flap breast reconstruction.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Breast disorders
Study type	Observational non invasive

Summary

ID

NL-OMON41914

Source
ToetsingOnline

Brief title
Incidence of pulmonary embolism after abdominal flap breast reconstruction.

Condition

- Breast disorders
- Breast therapeutic procedures
- Embolism and thrombosis

Synonym
bloodclot in the lungs, thrombus in the lungs

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Aanvraag wordt ingediend bij Achmea

Intervention

Keyword: breast, DIEP, pulmonary embolism

Outcome measures

Primary outcome

The occurrence of a pulmonary embolism.

Secondary outcome

To asses potential risk factors on pulmonary embolism: age, body mass index, BRCA1 and BRCA2 gene mutations, smoking, a history of cancer, presence of malignancy at the time of reconstruction, chemotherapy or hormonal therapy at the time of reconstruction, previous radiotherapy, timing of reconstruction (primary or secondary), laterality of reconstruction (unilateral or bilateral), operation duration, complication other than pulmonary embolism and number of re-operations will be recorded.

To investigate the potential etiology of pulmonary embolism in patients undergoing an abdominal based breast reconstruction.

Study description

Background summary

Autologous abdominal free flap breast reconstruction is regarded as superior compared to other breast reconstruction techniques available today. A complication that has been reported less often is pulmonary embolism. A possible explanation for this is that thromboembolic complications such as deep venous thrombosis and pulmonary embolism often have a subclinical course. A

recent retrospective multicentre study performed at the Erasmus MC and the Maastricht University Medical Centre, showed an incidence of pulmonary embolism of four percent, which is high compared to other studies, especially when taking into consideration that the thrombosis prophylaxis regimens did not differ between these studies.

Study objective

The primary aim of this study is to prospectively assess the incidence of pulmonary embolism in patients undergoing abdominal flap breast reconstruction.

Study design

A multicenter cohort study will be performed.

Study burden and risks

The first five days after surgery and at the outpatient clinic consultation two weeks after surgery the patients will be scored on clinical sign suggestion pulmonary embolism. Three months after surgery, patients will be asked, via a telephonic interview, if a thrombo-vascular event occurred after surgery.
Taking part in the study is a minimal burden to patients in the form of a questionnaire that will be completed six times and a telephone follow-up.
To investigate the potential etiology of pulmonary embolism in patients undergoing an abdominal based breast reconstruction patient suspected of having a pulmonary embolism will, apart from the normal CTA of the lungs, undergo a CTA of the iliac vessels and a Duplex ultrasound of the lower extremities. The CTA of the iliac vessels will be performed at the same time as the CTA of the lungs to minimize the burden to patients. The scanning of the iliac vessels adds a minimal radiation dose, which in our view is acceptable. The ultrasound of the lower extremities is a non-invasive investigation with minimal risk for the patient. It will however consume some time, approximately half an hour.
The aim of the research is to gain more insight in the incidence of pulmonary embolism, possible risk factors and the aetiology.
Given the potential deadly effects of this less common complication we find it justified with the burden and risks associated with participation.

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

All patients undergoing an abdominal flap breast reconstruction.
Aged 18 years or older

Exclusion criteria

Inability to confirm to the thrombosis prophylaxis protocol.
Patients who are on anticoagulant medication or have coagulopathy.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	422
Type:	Actual

Ethics review

Approved WMO

Date:	20-10-2015
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	NL50693.078.15

Study results

Date completed:	25-07-2022

Summary results
Trial never started