A randomized clinical trial to study positive effects of "T-REX Twente regimen" (Thoracic surgery Rehabilitation Experts Twente) on quality of life and mobilisation activities for cardiac surgery patients after full median sternotomy, compared to usual care

Published: 22-03-2024
Last updated: 02-12-2024

Do the T-REX Twente precautions have a positive impact on the quality of life (MAcNew QLMI), level of physical activity, and reduction of fear of movement in heart patients after a total median sternotomy compared to the (current) standard...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Interventional

Summary

ID

NL-OMON56700

Source
ToetsingOnline

Brief title
T-REX Twente: Thoracic surgery Rehabilitation Experts Twente

Condition

- Cardiac disorders, signs and symptoms NEC
- Cardiac therapeutic procedures

Synonym

cardio-thoracic surgery with median sternotomy, heart surgery

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: Stichting Hartcentrum Twente

Intervention

Keyword: Cardiac surgery, Quality of life, Sternal precautions, Sternotomy

Outcome measures

Primary outcome

The first primary endpoint is the standardized response mean difference of Quality of Life after Myocardial Infarction Questionnaire (MacNew QLMI) clinically postoperative (4th day postoperatively) until the start of cardiac rehabilitation (4-6 weeks postoperatively).

The second primary endpoint is the duration of not being in bed for up to 4 days in the ICU and the general ward, measured using two AX3 accelerometers.

Secondary outcome

Secundary endpoints include a difference in experienced pain as measured with NPRS, quality of life (MacNew QLMI) and kinesiophobia as measured with TSK preoperatively to end of cardiac rehabiliation.

Other endpoints include the actual activities per day (actual in minutes and relative to all mobilisation activities) for lying in bed, sitting, standing, walking, biking on ergometer, and walking the stairs until hospital discharge.

Last, a combined endpont of sternal refixation, superficial and deep sternal wounds for 30 days after surgery.

Study description

Background summary

Each year, more than 1000 open-heart surgeries (OHO) are performed at Thorax Centrum Twente (TCT), with 860 of them involving a total median sternotomy. Some patients present themselves at the cardiac care unit with unexplained complaints after discharge, possibly caused by anxiety and insecurity.
There is no consensus regarding postoperative sternal precautions following a total median sternotomy. Studies in the United States and Canada have indicated that these precautions might be too strict, and alternative, less restrictive precautions through the use of the "Keep your Move in the Tube" (KYMITT) approach have been shown safe and without adverse consequences.
Although no statistically significant differences were observed in all outcomes, patients following the new approach (KYMITT) reported fewer issues with functional mobility.

Study objective

Do the T-REX Twente precautions have a positive impact on the quality of life (MAcNew QLMI), level of physical activity, and reduction of fear of movement in heart patients after a total median sternotomy compared to the (current) standard precautions?
Do these precautions also have no adverse effects on pain, wound healing, and/or postoperative complications?

Study design

This is a prospective randomized double blind study, collecting data from patients undergoing a total median sternotomy from February 2024 to April 2026 at TCT and concurrently participating in outpatient cardiac rehabilitation under the guidance of TCT.

Intervention

The precautions are instructed by the physiotherapist to both groups immediately postoperatively and are constantly repeated by the involved disciplines during the hospital stay.
The control group is not allowed to lift, push, or pull for the first 6 weeks. There is little to no evidence for the current strict precautions currently implemented in the department.
The intervention group receives the new T-REX Twente precautions, allowing for more independent activities through the use of the tube model (keeping elbows close to the sides).

All patients receive three questionnaires (MacNew QLMI, Numeric Pain Rating Scale, and Tampa Scale for Kinesiophobia) preoperatively, on the 4th day postoperatively, on the first day of cardiac rehabilitation, and at the end of cardiac rehabilitation, taking approximately 10 minutes each time.
Additionally, during the clinical admission immediately postoperatively, two AX3 accelerometers are placed on the patient, one lateroproximal on the right upper arm and one anterodistal on the right upper leg.

Study burden and risks

There is little to no evidence for the current strict precautions currently implemented in the department.
Previous research in the United States and Canada has shown no additional complications using the KYMITT approach.
During the study, we do not expect an increase in complications in either group.

Contacts

Public
Medisch Spectrum Twente

Koningsplein 1
Enschede 7512 KZ
NL
Scientific
Medisch Spectrum Twente

Koningsplein 1
Enschede 7512 KZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients aged >= 18 years
Patients who receive cardiac surgery in Medisch Spectrum Twente with complete median sternotomy access
Patients with their cardiologist working at Medisch Spectrum Twente

Exclusion criteria

• Postoperative ICU stay > 72 hours
• Delirium (DSM V) or dementia (or other major cognitive disorders)
• Dutch language barrier
• Cardiologist outside Medisch Spectrum Twente

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-05-2024
Enrollment:	154
Type:	Actual

Ethics review

Approved WMO Date:	22-03-2024
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
ClinicalTrials.gov	NCT06115759
CCMO	NL78107.100.23