Long Term Follow-up PRIMA Trial

No registrations found.

Ethical review	Positive opinion
Status	Other
Health condition type	-
Study type	-

Summary

ID

NL-OMON22792

Source
NTR

Brief title
LTFU PRIMA Trial

Health condition

Incisional hernia

Sponsors and support

Primary sponsor: Prof. dr. J.M. Hendriks
Department of Surgery
Erasmus MC, Rotterdam
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Source(s) of monetary or material Support: Not applicable

Intervention

Outcome measures

Primary outcome

The primary outcome will be IH incidence up to five years after surgery, clinically and/or radiologically detected.

Secondary outcome

Secondary outcomes will comprise:

• Hernia repair surgery

o Size of hernia

o Type of mesh fixation

• Symptomatic IH;

o Pain or discomfort at the site of the scar

o Incarceration of the bowel

o Aesthetic symptoms

• IH progression (assessed with ultrasonography or CT-scan)

• Cost-benefit analysis (direct costs)

o General practitioner visits

o Emergency department visits

o Radiological examinations

o Outpatient clinic visits

o Hospitalization

Study description

Background summary

Rationale: Onlay and sublay mesh reinforcement after midline laparotomies in patients with an increased risk for the development of incisional hernias (IHs) resulted in less IHs compared

to patients that received the conventional closure technique at two years follow up.

Objective: The main objective of this long-term follow up study is to investigate IH incidence after closure of midline incisions in the three existing study groups (primary suture closure, onlay mesh reinforcement and sublay mesh reinforcement).
Study design: In the LTFU PRIMA trial, patients who were initially included will receive one additional follow-up examination. The PRIMA trial was designed as double blinded randomized controlled trial.

Study population: Subjects included in the PRIMA-trial will be asked to participate. In the PRIMA trial patients with an increased risk for the development of IHs are included.
Intervention (if applicable): In the LTFU PRIMA-trial patients included subjects will not undergo additional interventions. They will be invited to the outpatient clinic where they will undergo a physical examination and if agreed upon an ultrasonography of the post-operative scar.

Main study parameters/endpoints: Primary outcome will be IH incidence in high-risk groups after midline laparotomy, after a follow-up of five years Secondary outcomes comprise: IH repair surgery, symptomatic IH, IH progression and cost-benefit.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Patients will be invited to visit the outpatient clinic once. During this visit physical examination and an ultrasonography will be performed.

Study objective

Onlay and sublay mesh reinforcement after midline laparotomies in patients with an increased risk for the development of incisional hernias (IHs) resulted in less IHs compared to patients that received the conventional closure technique at two years follow up.

The main objective of this long-term follow up study is to investigate IH incidence after closure of midline incisions in the three existing study groups (primary suture closure, onlay mesh reinforcement and sublay mesh reinforcement).

Study design

5 years after surgery

Intervention

Follow-up: physical examination and ultrasonography

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

• Participated in the PRIMA trial

• Signed informed consent

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

• Pregnancy during follow up

• Subjects who underwent re-operation (midline abdominal surgery)

Study design

Design

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	19-07-2018
Enrollment:	350
Type:	Unknown

Ethics review

Positive opinion

Date:	01-05-2018
Application type:	First submission

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
NTR-new	NL7176
NTR-old	NTR7367

Register	ID
Other	Erasmus MC : mec20181040

Study results

Summary results

Jairam AP, Timmermans L, Eker HH, Pierik RE, van Klaveren D, Steyerberg EW, et al. Prevention of incisional hernia with prophylactic onlay and sublay mesh reinforcement versus primary suture only in midline laparotomies (PRIMA): 2-year follow-up of a multicentre, double-blind, randomised controlled trial. The Lancet. 2017;390(10094):567-76.