ARTIS: Activating Relatives To get Involved in care after Surgery

No registrations found.

Ethical review	Positive opinion
Status	Suspended
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20346

Source
Nationaal Trial Register

Brief title
ARTIS

Health condition

Family-centered care, fundamentals of care, surgery, oncology

Familiegecentreerde zorg, basiszorg, chirurgie, oncologie

Sponsors and support

Primary sponsor: Amsterdam UMC, location AMC, Amsterdam, The Netherlands
Source(s) of monetary or material Support: Amsterdam UMC, location AMC, Amsterdam, The Netherlands

Intervention

Outcome measures

Primary outcome

Primary outcome measure is the number of first unplanned readmissions within 30 days after discharge.

Secondary outcome

Secondary outcomes are postoperative complications, patients¡¯ quality of life, satisfaction of patients with care, unplanned readmissions caused by complications sensible to basic care activities, healthcare costs, amount of home care after discharge, hospital length of stay, sleep quality, anxiety and depression .

Study description

Background summary

The trial has been stopped prematurely, as we changed the design to a cohort study.

Background of the study:

In surgery, active involvement of family caregivers has the potential to improve outcomes by the prevention of unplanned readmissions and surgical complications. Some complications are believed to be potentially preventable and are sensitive to basic care. Basic care reflects a diverse range of care processes that combine the physical, psychosocial and relational dimensions of care, traditionally delivered by nursing staff. Although basic care activities seems to be simple, they are prone to be missed care. Since family caregivers are often the primary caregivers after discharge, they could be trained to deliver basic care. The period of hospitalization can be seen as an optimum environment to actively stimulate family caregivers to collaborate in care.

Objective of the study:

To evaluate whether a family involvement program comprising a set of evidence-based basic care activities reduces the number of unplanned readmissions and postoperative complications after major abdominal surgery.

Study design:

A randomized controlled, pragmatic superiority trial in the Amsterdam University Medical Center, location AMC.

Study population:

Adults (¡Ý 18 years), undergoing major surgery with an expected hospital stay of at least 5 days for one of the following indications: premalignant and malignant pancreatic, esophageal or colorectal tumor. We will include 244
patients per group, 488 patients in total.

Intervention:

A family involvement program to support the active involvement family caregivers in basic care activities for patients in post-surgical patient care. This program consists of six main components: (1) information about basic care
activities; (2) goal setting with the patient, family caregiver and nurse; (3)
task-oriented training; (4) hands-on participation in basic care focusing on early mobilization, oral intake, breathing exercises, oral care and active
orientation; (5) presence of family caregivers during medical ward rounds; (6) rooming-in (at least 8 hours a day). This intervention is added on top of usual postoperative care.

Control:

Usual postoperative care

Primary study outcome:

Primary outcome measure is the number of first unplanned readmissions within 30 days after discharge.

Secundary study outcomes:

Secondary outcomes are postoperative complications, patients¡¯ quality of life, satisfaction of patients with care, unplanned readmissions caused by complications sensible to basic care activities, healthcare costs, amount of home care after discharge, hospital length of stay, sleep quality, anxiety and depression.

Study objective

A family involvement program will reduce the number of unplanned readmissions in adult patients undergoing major abdominal surgery.

Study design

T0= baseline

T1= at discharge

T2= date of surgery + 30 days

T3= discharge + 90 days

T5= end of trial

Intervention

A family involvement program to support the active involvement family caregivers in basic care activities for patients in post-surgical patient care. This program consists of six main components: (1) information about basic care activities; (2) goal setting with the patient, family caregiver and nurse; (3) task-oriented training; (4) hands-on participation in basic care focusing on early mobilization, oral intake, breathing exercises, oral care and active orientation; (5) presence of family caregivers during medical ward rounds; (6) rooming-in (at least 8 hours a day). This intervention is added on top of usual postoperative care.

Contacts

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Eligibility criteria

Inclusion criteria

• Age equal or above 18 years;

• Scheduled for major surgery as treatment for the following indications: premalignant or malignant pancreatic, esophageal or colorectal tumor

• An expected hospital stay of at least 5 days postoperatively;

• Presence of a suitable family caregiver who is up to deliver basic care during hospitalization and after discharge (if needed)

• Presence of a suitable family caregiver who is able to be present during hospitalization (minimum of 8 hours per day) during the first 5 days on the nursing ward.

Exclusion criteria

Patients:

• Patients who are expected to remain in the intensive care unit (ICU) for over 72 hours after surgery

• Patients who will be operated in another hospital not participating in this study

• Patients unable to provide informed consent

• Patients who are unable to communicate in Dutch

Family caregivers:

• Family caregivers with an age equal or below 17 years

• Family caregivers who are not able to be present during hospitalization (minimum of 8 hours per day) during the first 5 postoperative days on the nursing ward

• Family caregivers who are not nominated as appointed family caregiver by patient

• Family caregivers who receive support from healthcare professionals to carry out self-care activities by

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	26-04-2019
Enrollment:	488
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	08-11-2018
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	NL7346
NTR-old	NTR7611

Register ID

Other Medical Ethics Committee Amsterdam UMC : ABR ID: NL66712.018.18

Study results