ARTIS: Activating Relatives To get Involved in care after Surgery

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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.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Interventional

Summary

ID

NL-OMON48666

Source
ToetsingOnline

Brief title
ARTIS-trial

Condition

- Miscellaneous and site unspecified neoplasms benign

Synonym
esophageal and/or colorectal tumor, pancreatic

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC, locatie AMC
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Family-centered care, Fundamentals of care, Randomized controlled trial, Surgery

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, anxiety, depression, satisfaction of patients with care, social isolation, unplanned readmissions caused by complications sensible to basic care activities, healthcare costs, amount of home care after discharge, hospital length of stay, and sleep quality.

Study description

Background summary

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.

Study objective

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 and the UMCG.

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

Study burden and risks

Included patients will undergo major elective surgery. If patients are allocated to the intervention group, family caregivers will be asked to deliver basic care during hospitalization and after discharge (if needed). Furthermore, we expect that they will be present for a minimum of 8 hours per day during the first 5 days on the nursing ward. This may instigate family caregiver burden. However, based on the results of our pilot study, it seems that the family involvement program is feasible for family caregivers, patients and healthcare professionals. Our results indicate that this program may lead to an absolute reduction of hospital readmissions of 15%; the incidence of postoperative pneumonia was slightly higher in the control group compared to the intervention group. We therefore hypothesize that the family involvement program can lead to a reduction of the number of first unplanned readmissions, and considered a 10% reduction as clinical relevant.

Contacts

Public
Amsterdam UMC, locatie AMC

Meibergdreef 9
Amsterdam 1105AZ

NL
Scientific
Amsterdam UMC, locatie AMC

Meibergdreef 9
Amsterdam 1105AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion 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 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 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 themselves.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-04-2019
Enrollment:	488
Type:	Actual

Ethics review

Approved WMO Date:	22-10-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-02-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO Date:	09-12-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL66712.018.18