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A randomised controlled trial of geriatric liaison intervention in frail surgical oncology patients

Submission date 28/12/2006	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/12/2006	**Overall study status** Completed	
Last Edited 05/01/2021	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NL810, NTR823

Study information

Scientific Title
A randomised controlled trial of geriatric liaison intervention in frail surgical oncology patients

Study objectives
The primary objective of this study is to show that early detection of geriatric patients at risk of preventable functional decline following a surgical procedure under general anesthesia for a solid tumor, combined with a geriatric liaison intervention will decrease the occurrence of delirium and consequent morbidity and mortality, without an increase in costs.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Randomised, controlled, parallel group, multicentre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Frail surgical oncology geriatric patients

Interventions
The intervention entails participation of a geriatric nurse and geriatrician in the perioperative treatment of the oncogeriatric surgical patient. Multi-component interventions to achieve best-supportive care in individual treatment plans will be implemented. These will be focused on electrolyte- and fluid levels, pain management, pharmacological clearance, miction and defecation, nutrition, early mobilisation and rehabilitation, sleep, vision, hearing and cognition.

The Delirium Observation Scale (DOS) will be used to screen for delirium by the nurse and the Delirium Rating Scale (DRS) will be used to measure the severity of the delirium. To ensure uniformity of geriatric intervention in participating centres a daily checklist will be used.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The cumulative incidence of delirium (measured with the Delirium Observation Scale and the Diagnostic and Statistical Manual of Mental Disorders Fourth Edition [DSM IV] criteria) up to ten days postoperatively.

Secondary outcome measures
1. Returning to the pre-operative living situation within 3 months postoperatively
2. The Physical Component Summary measure (PCS) of the Short Form health survey (SF-36)
3. The Mental Component Summary measure (MCS) of the SF-36
4. Complications during hospital stay including mortality
5. Care Dependence Scale at discharge
6. Direct health care and non-health care costs will be used as economic indicators

Overall study start date
01/01/2007

Completion date
01/01/2010

Eligibility

Key inclusion criteria
1. A score greater than three on the Groningen Frailty Index (GFI)
2. Surgery is scheduled more than 24 hours after inclusion in the study as we feel this is the time necessary for the geriatric team to plan their perioperative measures
3. Surgery under general anesthesia
4. Written informed consent given according to local regulations

Participant type(s)
Patient

Age group
Senior

Sex
Not Specified

Target number of participants
294

Total final enrolment
260

Key exclusion criteria
1. Any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule
2. Patient unable to comply with the outcome questionnaires

Date of first enrolment
01/01/2007

Date of final enrolment
01/01/2010

Locations

Countries of recruitment
Netherlands

Study participating centre
University Medical Center Groningen (UMCG)
Groningen
Netherlands
9700 RB

Sponsor information

Organisation
University Medical Center Groningen (UMCG) (The Netherlands)

Sponsor details
Department of Surgery
P.O. Box 30.001
Groningen
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Sponsor type
Hospital/treatment centre

Website
http://www.rug.nl/umcg/index?lang=en

ROR
https://ror.org/03cv38k47

Funder(s)

Funder type
Research organisation

Funder Name
Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands)

Alternative Name(s)
Netherlands Organisation for Health Research and Development

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Netherlands

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	22/02/2016	05/01/2021	Yes	No