

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

Submission date 28/12/2006	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/12/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 05/01/2021	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised, controlled, parallel group, multicentre trial

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Senior

Sex

Not Specified

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)

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

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