Geriatric Oncology on Track; transmural and digital ways of keeping senior cancer patients on systemic treatment

Published: 12-06-2014
Last updated: 15-05-2024

The aim of this project is to maintain quality of life and improve cancer related outcome by preventing therapy-related toxicity (and ensuing unplanned hospital admission and /or discontinuation of chemotherapy) in cancer patients treated with...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON44642

Source
ToetsingOnline

Brief title
Geriatric Oncology on Track

Condition

- Other condition
- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
cancer treatment in elderly patients

Health condition

kankerbehandeling bij oudere patiënten

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: KWF

Intervention

Keyword: adverse reactions, monitoring, quality of life, senior cancer patients

Outcome measures

Primary outcome

Less unexpected hospitalizations

Secondary outcome

1. Patiënt reported outcome measures (PROM) about intensive monitoring

2. Hospital replaced care in transmural collaboration

3. Implementation of a web-based platform for intensive monitoring of treatment

related adverse effects

4. Knowledge on possible differences between Dutch regions and community versus

university hospital

5. Comparison of data from Easycare-Tos with two

screeningsinstrument used in older cancer patients (G8 and GFI) and data from a

limited geriatric assessment (IADL, GDS en MNA)

Study description

Background summary

The number of patients aged over 65 years diagnosed with cancer is increasing over the last years. In the year 2000, cancer was diagnosed in the Netherlands in about 69,000 patients, including 40,000 patients aged over 65 years. In 2015 an incidence of 95,000 patients is expected, including over 58,000 patients aged over 65 years (1).

This large number of senior cancer patients will more and more cause a strain on our health care system and urge for collaboration between home care providers and hospitals.

The majority of older cancer patients present in community hospitals. There seems to be an underrepresentation of older cancer patients in University hospitals compared to large community hospitals. In 2012 about 10% of new patients in the department of medical oncology of the Radboud University Medical Center (RUMC) is aged over 65 years, whereas in the Medisch Spectrum Twente (MST) this percentage is about 45%. Of note, the percentage of 65+ patients in the departments of surgery and urology are expected to be higher than this 10% and 45% respectively. Besides this underrepresentation in university medical centers, it is highly likely that also other patients characteristics are different between university hospitals and community hospitals. In a current collaborative project assessing preferences for treatment in MST and RUMC, patients in the RUMC had a higher the mean education level than in MST (2). University hospitals are more focused on research then community hospitals.
Because of all the above, we regard cooperation between university hospitals and community hospitals requisite in innovative projects regarding cancer in the elderly, and we urge for collaboration with GPs.

Systemic therapy (cytostatic and/or targeted treatment) can be beneficial to cancer patients, regardless of age, however, older patients are at risk for treatment-related toxicity. Treatment related side-effects and unplanned hospital admissions (UHA) have a major impact on quality of life, threatening independence (3,4). Treatment related side-effects often lead to dose reductions, and in older patients even low grade toxicities (grade I/II) led frequently to treatment modifications (5).

Geriatric assessments are increasingly advocated for use in oncology. A Complete Geriatric Assessment (CGA) is defined as a multidisciplinary evaluation in which multiple problems of older people are uncovered, described and if possible explained, and in which the resources and strength of the person are catalogued and a coordinated plan is developed to focus interventions on the individual persons problems (6). In general, the positive health effects of GCA have been established, for example in prevention of functional decline and (re)hospitalisations (7) but in oncology data are still scarse. In geriatric medicine, a GCA is discussed in a multidisciplinary team and this leads to individual treatment goals and individual intervention plans are made. Until now in oncology, GCA is mostly used for discovering unknown health problems, and for prediction of survival or tolerance for chemotherapy, without making individual treatment goals or intervention plans (8). However, also in regular oncology practice data derived from a GCA could lead to personalized interventions aimed at improving quality of life and prevention of toxicity.
Despite all these arguments underscoring the relevance of performing a CGA

there are still barriers to implement a CGA in common practice. These arguments encompass the following issues.
* GCA data on tolerance for treatment are not consistent, and several studies in oncology reveal different tests to be most useful of different outcomes measures. For example, in Dutch lung cancer patients aged * 70 years receiving first line palliative chemotherapy, CGA appeared of limited value for predicting toxicity or finishing all cycles of chemotherapy. Patients with worse scores on the Geriatric Depression Score-15 were more likely to experience neuropsychiatric toxicity. Patients with better scores on ADL (activities of daily living) or IADL (instrumental activities of daily living) were more likely to finish all scheduled chemotherapy cycles (9). Worse scores on GDS and Groningen Frailty Indicator were associated with reduced survival, as was the classical Performance Score. In another Dutch study evaluating 70+ patients with different primary tumors treated with chemotherapy found that lower scores for tests for nutrition (Mini Nutritional Assessment, MNA) and cognition (Mini Mental State Examination, MMSE) were associated with less cycles of chemotherapy. In addition, inferior scores on MNA and MMSE were associated with an increased mortality after the start of chemotherapy (10). In a French study including similar patients (70+, different tumor types, chemotherapy) MNA and poor mobility predicted early death (11). Another French study in 75+ patients receiving first line chemotherapy for metastatic colorectal cancer, MMSE and IADL were predictive for grade III/IV toxicity and deviant scores on GDS and MMSE were associated with unexpected hospitalization, which occurred in 44% of patients (12).
* A CGA is time consuming and this aspect appeared both for patients and family, as well as for physicians an important reason for not participating in a Dutch study regarding CGA in patients with metastatic breast cancer receiving first line chemotherapy (13). Therefore, a two step approach has been advocated, using a screening method followed by a CGA in those patients scoring impairments on the screening tool. Several screening tools have been used, like the Vulnerable Eldery Survey-13 (VES-3), the Geriatric 8 (G8) and the Groningen Frailty Indicator (GFI), but until no final judgment can be made whether these instruments have sufficient discriminative power to select patients for further assessment (14). The largest study on screening followed by assessment in cancer patients included 1967 Belgian patients used the G8 screening tool. Only 29% of patients appeared * fit* and did not require a CGA (15). Using the GFI 63% appeared fit in Dutch cancer patients scheduled for chemotherapy (10)

If the time consuming aspect of a geriatric assessment is a major obstacle for daily oncology practice, the question is how to reduce this. One option is to use already available information at the General Practitioner (GP) practice. Recently the Easycare-Two-step Olders person screening (Easycare-TOS) was developed in a collaborative project of the departments of Geriatrics and General Practice at the RUMC, and appeared an indentification instrument for frailty in primary care (16). This Easycare-TOS was developed because all the existing screening tools don*t implement information that is already available at the GP including tacit (implicit) knowledge and other potential available

information of primary health care workers. The first step in the Easycare-TOS instrument is a list of 14 questions answered by the GP, and after filling in the GP judges whether the patient is * not frail*, *frail* or *unclear*. All patients scoring *frail* or *unclear* proceed to the second step with a structured assessment. So, this Easycare-TOS has the advantages that the professional*s appraisal is important and the care context of the patient in involved (16). Involvement of these two could be very relevant as the majority of older cancer patients suffer from co-morbidity and often patients are involved in several multi agency healthcare systems (*ketenzorg*), for example for COPD, diabetes and heart failure, and unfortunately the communications between all those systems is often far from ideal.

In the Radboud UMC, all older patients (>70years) who started chemotherapy in period May 2011-May 2013 were reviewed, and an 36% incidence of UHA was observed (17). UHA occurred despite a pretreatment-assessment (using Easycare-TOS) provided to all patients with interventions taken for unmet needs if necessary and despite follow up by a oncology nurse in the first week of treatment by phone calls. Most UHA were treatment related (83%), occurred in first treatment cycles (47%) and markedly, after patient*s delayed toxicity reporting (50%). Frequently complaints existed already for over 48 hours without early report to their oncologist, despite explicit pre-treatment instructions by a geriatric oncology nurse specialist to do so. Although the majority of patients recovered and were discharged back home (93%), UHA led to treatment modification in 80%; 37% discontinuing without alternative systemic therapy being started. Further analyses showed a mean day of admission on day 8 after chemotherapy and the two most frequent reasons for admission were dehydration due to gastro-intestinal adverse events and fever.

The finding that patients do not report side effects timely and reliably was previously demonstrated in a study in which patients receiving chemotherapy used a Therapy-Related Symptom Checklist (TRSC) during the first 7 days of treatment (immediate) and at their next visit to the hospital (delayed). It appeared that patients reported less symptoms and less severe symptoms when they reported at the next hospital visit (18). This underreporting of toxicity leads to an unwanted lack of reductions and chance of even more serious toxicity after the next cycle of chemotherapy.

By monitoring toxicity early and taking supportive care measurements before severe (sequels of) toxicity develop, UHA and its consequences on both QoL and further treatment might be prevented (3,4). However, numbers of older cancer patients will increase and the use of internet and/or social media might be an effective way to support medical staff. In a Norwegian randomized trial in patients with leukemia or lymphoma, the use of a computer assisted interactive tailored patient assessment tool resulted in increased symptom reporting but reduced distress due to these symptoms and reduced need for symptom management support (19)

Dutch society will digitalize rapidly: in 2009 about 1/3rd of 65-75 year old never used a personal computer, but this number was only 13% in ages 55-65 years old; in 2013 already more than 50% of 65-75 year old use the internet regularly. In 2012 about one third of persons aged 75+ used internet (20) . Reshape developed *Hereismydata **; a platform where patients can keep their personal health record together with a connectivity tool in which they can upload any kind of data to health care professionals of their choice. This tool can be used in primary health care as well in hospital care and provides tools for monitoring patients by their carers. A specific questionnaire will be developed focusing on the most frequent chemotherapy-related side effects leading to UHA (for example for diarrhea, dehydration and fever).

Study objective

The aim of this project is to maintain quality of life and improve cancer related outcome by preventing therapy-related toxicity (and ensuing unplanned hospital admission and /or discontinuation of chemotherapy) in cancer patients treated with systemic therapy by the following procedures.

1. Integration of care/ transmural collaboration

1.1. Participation of GP in the assessment of cancer patients starting treatment by using the first step of Easycare-TOS
1.2. Patients presenting in the MST will be visited by the oncology nurse at home. At this visit other caregivers (POH, district nurse, home care) will be invited for a round table, for explanation and education about side effects, and care needs will be assessed. If other caregivers are unable to attend, they will be actively informed by telephone before start of treatment. For patients from the UMCN there will be no home visits, but all other caregivers are actively informed before treatment starts.
1.3. Frequent contact of hospital-based specialized oncology nurse with POH/ home care/ district nurse
1.4. Home visits of GP/POH/district nurse to manage toxicity and/or evaluation /preparation for next treatment cycle in close contact with hospital team.

2. Integrating *Hereismydata ** in daily care to monitor treatment-related toxicity using a short questionnaire to be filled in by the patient on a 2-daily basis in the first cycle of treatment and on demand there-after; in case the questionnaire needs follow up or no questionnaire is received the hospital nurse will either contact the patient or POH/ homecare/district nurse for further actions to assist in a structured transfer of care and responsibilities a (online) form will be developed and tested
In patients that are no internet users, their children or other care givers will are asked to fill in these data.

3. Education of home care providers to provide them with tools to adequately

intervene / counsel oncology patients by developing a teaching module in collaboration with the HAN/ dr. R. van de Sande

4. Evaluation of the use of Easycare-TOS in cancer patients.
4.1. there will be measurement of acceptability of Easycare-TOS among GPs
4.2. Data from the first step of Easycare-TOS will be compared with data from two screening tools used in oncology (G8 and GFI), and data from a limited CGA (including IADL, GDS and MNA) The Easycare-Tos will be performed before start of treatment by the GP and the screening tools and CGA by the oncology nurse before start of treatment.

5. Exploring patient preferences on care by hospital nurse, POH, district nurse and the use of internet.

Study design

1. After the first consultation of older patients with cancer who are planned to start with systemic therapy, patients will be informed to participate in this project.
2. After giving informed consent, the GP will be contacted and informed about the treatment goals and toxicity. Information from the GP will be obtained, according to the Easycare-TOS (first step).
3. Patients will be informed by the oncology nurse about their treatment and possible side effects. Information about *Hereismydata ** will be given.
4. A limited CGA, including (G8, GFI, IADL, GDS and MNA) will be performed by the trained oncology nurse.
5. For the MST patients, they will be visited by the oncology nurse at home, preferably in cooperation with the regular home care team and a team member of the GP. Emphasis will be put on toxicity items, and *Hereismydata ** use. For the UMCN patients, the oncology nurse will inform the CP team and the home care team by telephone. There will be one person in primary care which serves as the first partner responsible for maintaining links in primary care (POH or home care team member) and the oncology nurse will be coordinator of care in hospital.
6. Patients will be asked to use *Hereismydata * every two days for the first cycle of treatment. For patients without internet access caregivers (e.g. children) will be asked to fill in the data, and if using internet is not possible at all there will be regulary telephonic contact by the oncology nurse. The oncology nurse will contact the first partner in primary care if necessary.
7. In case of toxicity outside office hours, patients will contact the hospital.
8. Data will be analyzed regarding UHA.
9. Data will be analyzed regarding feasibility of Easy-TOS in patients scheduled for systemic therapy and these data will be compared with those of the screening tools and from CGA
10. Data will be analyzed regarding PROM, measurement will performed before start of treatment, after cycle one and every 3 months thereafter. Specific

questionnaires are to be determined, but most likely will include EORTC-QLQ-C30, EQ-D5, and/or the CQ index care for cancer patients which currently is under development.
11. Data will be analyzed regarding satisfaction among GPs and home care teams
12. A teaching module will be developed regarding recognition and treatment of sided effects of systemic cancer therapy, for use in primary care settings.

Study burden and risks

The burden for the patients is mainly related to time required for filling in the questionnaires.
For treatment starts, this will include about 30-45 minutes; after 2 cycles and 3 months after treatment finished this will take about 15 minutes.
During treatment there will be more frequently contacts with the oncology nurse

The benefit could be that patient experience more intensive monitoring (and better treatment of side-effect and less hospitalizations)

Contacts

Public
Medisch Spectrum Twente

Ariënsplein 1
Enschede 7511 JX
NL
Scientific
Medisch Spectrum Twente

Ariënsplein 1
Enschede 7511 JX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

treatment with chemotherapy/targeted therapy
aged 70 years or older
signed informed consent

Exclusion criteria

insufficient command on the Dutch language

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-08-2014
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	12-06-2014
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	08-12-2014
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	21-04-2015
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	27-09-2016
Application type:	Amendment
Review commission:	METC Twente (Enschede)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 24734
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL48682.044.14
Other	volgt
OMON	NL-OMON24734