CHOICE: CHOosing treatment together In Cancer at the End of life

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Disease-targeted treatment for metastasized or inoperable tumours offers uncertain and sometimes little benefit while treatment burden can be high. Hence, treatment decisions cannot be solely based on evidence and patients’ clinical status, but…

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22913

Bron
Nationaal Trial Register

Verkorte titel
CHOICE

Aandoening

advanced cancer; metastasized or inoperable tumours;

Ondersteuning

Primaire sponsor: Academic Medical Center, University of Amsterdam
Overige ondersteuning: Dutch Cancer Society

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Observed SDM in the audio-recorded consultation as assessed with a validated scoring instrument (OPTION) as well as a study-specific adaptation of that instrument.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Disease-targeted treatment for metastasized or inoperable tumours offers uncertain and sometimes little benefit while treatment burden can be high. Hence, treatment decisions cannot be solely based on evidence and patients' clinical status, but should incorporate patients' values and preferences This requires shared decision making (SDM), an approach whereby clinician and patient exchange information and jointly deliberate to come to an agreed-upon decision. Evidence shows that SDM is not standard practice in consultations about palliative systemic treatment.

Obective; This trial aims to test the (independent and combined) effectiveness of a patient-targeted preparatory tool ('Gesprekswijzer') and an oncologist-targeted communication skills training to enhance SDM in consultations about palliative systemic treatment. Secondary outcomes include, among others, patient satisfaction, anxiety, efficacy and quality of life.

Study design: A pragmatic multi-center randomised controlled design with four parallel arms will be adopted. Medical oncologists will be randomised to the training or the care as usual condition. Patients (n=192 within n=24 oncologists) will be randomised to either receive the QPL or care as usual.

Study population: The study population consists of all patients with metastasized or inoperable tumours and a median life expectancy of <1 year without disease targeted treatment, for whom systemic palliative treatment does not offer median survival benefit of >6 months who meet with the oncologist to discuss either the start of (a new line) of treatment or the (dis)continuation or adjustment of current treatment.

Country of recruitment: The Netherlands

Intervention: The CHOICE skills training is provided in small groups (n=3-5) by a professional trainer and actor. It consists of a reader, two half days of training making use of modeling videos and role play, a booster session and a consultation room tool.The 'Gesprekswijzer' consists of a Question Prompt List and Value Clarification Exercises, i.e., two known methods to empower patients in communication and decision making.

Main study endpoint: Observed SDM in the audio-recorded consultation as assessed with a validated scoring instrument (OPTION) as well as a study-specific adaptation of that instrument.

Time points: The skills of all participating oncologists will be assessed in simulated patient encounters at two time points. Additionally, consultations with participating patients will be audiotaped and oncologists will be asked to fill out a one page questionnaire after the consultation. All participating patients will fill out questionnaires at baseline, right before the consultation, 1 week after and at 3 and 6 months post-consultation. These include measures of secondary outcomes such as patient satisfaction and quality of life. Patient's treatment status and history will be registered from their medical files at 12 months.

Doel van het onderzoek

Disease-targeted treatment for metastasized or inoperable tumours offers uncertain and sometimes little benefit while treatment burden can be high. Hence, treatment decisions cannot be solely based on evidence and patients' clinical status, but should incorporate patients' values and preferences This requires shared decision making (SDM), an approach whereby clinician and patient exchange information and jointly deliberate to come to an agreed-upon decision. Evidence shows that SDM is not standard practice in consultations about palliative systemic treatment.
Objective: to test the (independent and combined) effectiveness of a patient-targeted preparatory tool ('Gesprekswijzer') and an oncologist-targeted communication skills training to enhance SDM in consultations about palliative systemic treatment.

Onderzoeksopzet

Oncologists: before and after training (in control group: twice with 8 weeks in between) in a standardized patient assessment; a questionnaire after each audiorecorded consultation

Patients: questionnaires at baseline, before consultation, after consultation and at 3 and 6 months. Patient's treatment status and history will be registered from their medical files at 12 months.

Onderzoeksproduct en/of interventie

The oncologist skills training is based on a four-step model of SDM and on techniques known from behavior change theories. The training is provided in small groups (n=3-5) by a professional trainer and actor. It consists of a reader, two half days of training making use of modelling videos and role play, a booster session and a consultation room tool.

The ‘Gesprekswijzer’ consists of a Question Prompt List and Value Clarification Exercises, i.e., two known methods to empower patients in communication and decision making. The booklet compirses (1) an explanation that, when cure is no longer an option, treatment decisions are highly dependent on individual preferences, (2) example question patients may wish to pose in the upcoming consultation with the oncologist and (3) questions to help patients think about their values.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

1. diagnosed with metastasized or locally irresectable cancer

2. not eligible for treatment with curative intent

3. median life expectancy of <1 year without systemic treatment, and a median survival benefit of systemic treatment of <6 months. This includes, but not limited to, patients:

o with metastases or locally irresectable tumors of the pancreas, esophagus, stomach, liver, gall bladder, and bladder, and patients with metastatic sarcoma or melanoma

o patients with advanced cancer, irresective of tumour type, who have experienced progression under first line palliative systemic treatment.

4. scheduled for a consultation with a participating medical oncologist in which decisions about the start, (dis)continuation or adjustment of palliative systemic treatment will be made. This includes consultations in which:

o a decision to start, forego or postpone a (new line of) systemic treatment will be made

o current systemic treatment is evaluated after a fixed number of cycles and a decision to (dis)continue and/or adjust systemic treatment will be made

Oncologists

Eligible are all medical oncologists (in training) treating the eligible patient population with an appointment of at least 1 year after the start of the trial.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients

A potential subject who meets any of the following criteria will be excluded from participation in this study:

1. insufficient mastery of Dutch, i.e., inability to understand the 'Gesprekswijzer' as well as the questionnaires as judged by either the physician or the researcher

2. cognitive disabilities or a psychiatric disorder that hinder understanding of the 'Gesprekswijzer' as well as the questionnaires as judged by either the physician or the researcher

3. not enough time (<2 days) to make sure the Gesprekswijzer is received before the consultation in which decisions are made

4. a primary brain tumor or brain metastasizes which significantly hinder cognitive

functioning

5. being not, or no longer, eligible for (an additional line of) palliative systemic treatment (standard or experimental)

Oncologist

Excluded will be oncologists involved in the design of the content of the interventions.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-12-2015
Aantal proefpersonen:	192
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	15-09-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 44961
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5388
NTR-old	NTR5489
CCMO	NL48722.018.15
OMON	NL-OMON44961

Resultaten