

Betere patiënt-dokter dialoog over palliatieve zorg en deelname aan vroeg-klinische studies door online te verhelderen wat een patiënt belangrijk vindt

No registrations found.

Ethical review	Positive opinion
Status	Other
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27139

Source

NTR

Brief title

OnVaCT

Health condition

Early phase clinical trial
Palliative care
Value clarification tool
Patient-physician communication

Sponsors and support

Primary sponsor: Erasmus MC, Rotterdam

Antoni van Leeuwenhoek, Amsterdam

UMC Utrecht

Source(s) of monetary or material Support: KWF Kanker Bestrijding

Intervention

Outcome measures

Primary outcome

For WP1, the main study endpoint will be the delivery of a ready to implement online value clarification tool. For WP2 this will be decisional conflict measured by the Dutch version of the Decisional Conflict Scale (DCS).

Secondary outcome

Secondary study parameters for WP1 include the life values of patients, experiences with patient-physician communication, and the fit and value of the online value clarification tool.

Secondary outcomes for WP2 include the communication process, decision making process, discussion of patients' values and preferences, consultation duration, and actual usage of the tool.

Study description

Background summary

Patients for whom standard anti-cancer treatment is no longer available may be offered participation in early phase clinical trials. In the preceding consent procedure, both technical information and values and preferences of patients need to be discussed. Given the complexity of these trials, focus on the information may prevail without a clear patient-physician discussion on patient values, actual prognosis and palliative care options. Decisional conflict has been reported in patients after deciding on participation. This project aims to develop and evaluate an online tool to clarify patients' values around end-of-life decisions and support them in the decision to participate (or not) in a clinical trial.

Study objective

We hypothesize that clarifying the values of patients with incurable cancer without regular treatment options will empower patients and will create more effective patient-physician communication which helps to better attune communication to the individual patient needs. We hypothesize that an online value clarification tool aids in better value clarification and thus helps patients in this decision making process, which will be evaluated by assessing patients' decisional conflict.

Study design

Start inclusion: from October 1, 2018

Intervention

n.a.

Contacts

Public

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Eligibility criteria

Inclusion criteria

For the patients:

- Diagnosed with advanced cancer for whom standard systemic therapy is not or no longer available;
- medically fit enough to be offered participation in early phase clinical trials;
- aged 18 years or older;v
- sufficient command of the Dutch language;
- written informed consent.

For the (healthy) oncologists:

- member of a trial oncologists (study) team.

Exclusion criteria

For the patients:

- Cognitive impairment (e.g. dementia) according to the medical record;
- no access to the Internet.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Other
Start date (anticipated):	01-10-2018
Enrollment:	314
Type:	Unknown

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion	
Date:	17-07-2018
Application type:	First submission

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
NTR-new	NL7335
NTR-old	NTR7551
CCMO	NL65568.078.18

Study results

Summary results

<https://bmcpalliatcare.biomedcentral.com/articles/10.1186/s12904-019-0486-6>