Study of the possible factors of influence on the decision to partipate in early clinical cancer trials.

No registrations found.

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

Summary

ID

NL-OMON20050

Source
NTR

Health condition

Patients with solid tumors without standard treatment options considering participation in a phase I or phase II trial

Sponsors and support

Primary sponsor: ErasmusMC, Rotterdam, The Netherlands
Source(s) of monetary or material Support: ErasmusMC, Rotterdam, The Netherlands

Intervention

Outcome measures

Primary outcome

Outcome:

The influence of ‘motivation for treatment, hope, coping, locus of control and quality of life’ on the decision whether or not to participate in a phase I or phase II cancer trial.

Outcome Name:

Participation or non participation in a phase I or II cancer trial, motivation for treatment, hope, coping, locus of control and quality of life’.

The influence of ‘motivation for treatment, hope, coping, locus of control and quality of life’ will be measured using a questionair on different timepoint. The questionnaire contains 5 subquestionnaires:

1. Validated 12 items motivation questionnaire by Prochaska en DiClemente;

2. Validated 30 items coping questionnaire by Brandtstadter and Renner;

3. Validated 19 item questionnaire by of the Rotter locus of controle scale;

4. Validates 12 items questionnaire of the Herth Hope Index;

5. Quality of life is measured with the EORTC QLQ-C30, 3.0.

Secondary outcome

1. Differences and relation between ‘motivation for treatment, hope, coping, locus of control and quality of life’ at the start and end of the informed consent period;

2. Differences and relation between ‘motivation for treatment, hope, coping, locus of control and quality of life’ between patients who consent or do not consent to treatment in a phase I or phase II cancer trial;

3. Differences and relation between ‘motivation for treatment, hope, coping, locus of control and quality of life’ between patients who will or will not continue treatment after first response evaluation.

Study description

Background summary

Trial participation of cancer patients lacking standard treatment options is crucial for the development of new anti-cancer drugs. The main reason to participate is hope for remission or even cure. This study investigates the relationship of motivation for treatment, coping, locus of control, hope and quality of life in patients considering a phase I or II clinical cancer trial. Insight in these relationships could improve individualised patient information, within the legal settings, during the informed consent procedure and trial participation.

Study objective

Exploring QOL, hope, treatment motivition, coping en locus of control of patients considering early clinical cancer trial participation.

Study design

1. Before deciding participation in a phase I or II trial;

2. After deciding to participate in a phase I or II trial;

3. When participating after the first evaluation of the effect of the treatment.

Intervention

N/A

Contacts

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Eligibility criteria

Inclusion criteria

Patients considering participation on a phase I or phase II trial for the first time.

Exclusion criteria

1. Prior participation in phase I or II trial;

2. Age under 18 years.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-04-2011
Enrollment:	100
Type:	Actual

Ethics review

Positive opinion

Date:	27-02-2012
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	NL3203
NTR-old	NTR3354
Other	METC ErasmusMC : 11-106
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A