The iLIVE project: Live well, die well. A research programme to support living until the end

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To contribute to high-quality personalized care at the end of life by:a. Providing in-depth understanding of the concerns, expectations and preferences of patients in the last phase of life and their relativesb. Understanding the cultural, gender,...

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

Summary

ID

NL-OMON54372

Source
ToetsingOnline

Brief title
iLIVE cohort study

Condition

- Other condition

Synonym
care in the last phase of life, Palliative care

Health condition

patienten met een levensverwachting van 6 maanden of minder, ongeacht de aandoening

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: European Union (Horizon2020)

Intervention

Keyword: Concerns, Expectations, Last phase of life, Preferences

Outcome measures

Primary outcome

Primaire outcome: frequencies of concerns, expectations and preferences of

patients in the last phase of life after inclusion and after one month

Secondary outcome

Secondary endpoints are:

- Symptoms (ESAS, at baseline and after one month);

- Health-related quality of life (EORTC QLQ-C15-PAL quality of life item and

EQ-5D-5L, at baseline and after one month);

- ICECAP-SCM scores;

- Use of medical interventions and medicines and costs of medical care in the

last week of life (medical file data);

- Bereaved relatives* experiences and their appreciation of care and support in

the last days of life of the decedent, and bereavement levels (bereavement

questionnaire);

- Patient survival.

Study description

Background summary

In the EU about 4 million people yearly die from a chronic illness. Many of these people die in pain or distress. Care for dying patients and their close relatives is often suboptimal.

Study objective

To contribute to high-quality personalized care at the end of life by:
a. Providing in-depth understanding of the concerns, expectations and preferences of patients in the last phase of life and their relatives
b. Understanding the cultural, gender, age, healthcare -related and socio-economic variance in these concerns expectations and preferences

Study design

The iLIVE project involves a cohort study in which patients with an estimated life expectancy of six months or less are followed until they die. In total, we will include 2200 patients in 11 countries, i.e. 200 per country. Participants are requested to also involve a close relative. Both patients and relatives are asked to fill in a questionnaire, at baseline and after four weeks. If patients die during the study, the relative and physician are asked to fill in a post-bereavement questionnaire. Medical files are studied to assess health care use in the last days of life.

Study burden and risks

The study population concerns vulnerable people who may experience fluctuating symptoms and levels of suffering across their disease trajectory. We acknowledge the risk of overburdening or stigmatizing participants. If patients feel burdened by participating in the study, they are encouraged to indicate that.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Patient
1. Patient is 18 years or older.
2. The patient is aware that recovering from his/her disease is unlikely, to be assessed by the attending physician.
3. The attending physician would not be surprised if the patient were to die within 6 months.
4. If the physician is uncertain about the surprise question, the patient is eligible if presenting with at least one SPICT indicator

Relative
Relatives of participating patients are eligible to participate in the study if they are 18 years or older and provide informed consent to participate, and if the patient agrees. Relatives can be a family member, friend or other close relative. They have to be aware that the patient is unlikely to recover from his/her disease.

Exclusion criteria

Patient
1.The patient is incapable of filling in a questionnaire in the country*s main language or in English (patients may be supported by relatives when filling in the questionnaire).
2. The patient is incapable of providing informed consent to participate in the study, as assessed by the attending physician.

Relative

Relatives are not eligible if they are incapable of filling in a questionnaire in the country*s main language or in English.

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):	16-04-2021
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	02-10-2020
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	10-10-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	12-04-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
ClinicalTrials.gov	NCT04271085
CCMO	NL72756.100.20