The iLIVE medication optimisation trial

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The objective is to examine whether the use of CDSS-OPTIMED, a personalized medication advice to attending physicians of patients in the last phase of life, contributes to patients* quality of life.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON54708

Source
ToetsingOnline

Brief title
iLIVE medication study

Condition

- Other condition

Synonym
Chronic disease, with a life expectancy of 6 months or less

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 (Horizon 2020)

Intervention

Keyword: Clinical Decision Support System, Deprescribing, Medication management, Palliative care

Outcome measures

Primary outcome

Patients* quality of life four weeks after baseline assessment as measured by

the EORTC QLQ-C15-PAL questionnaire, quality of life question.

Secondary outcome

Secondary endpoints:

- Symptoms (ESAS, four weeks after baseline assessment);

- Health-related quality of life (EORTC QLQ-C15-PAL quality of life question

and EQ-5D, four weeks after baseline assessment);

- Use of medication four weeks after baseline assessment (medical file data and

pharmacist*s information system);

- Use of medical interventions and costs of medical care (retrospective medical

file data check about/of the last week of life);

- Patient survival;

- Satisfaction of the patient with medication (TSQM-9, four weeks after

baseline assessment);

- Satisfaction of the relative with medication (TSQM-9, adapted for relatives,

four weeks after baseline assessment);

- Satisfaction of the attending physician with the medicationadvices, generated

by CDSS-OPTIMED (questionnaire, four weeks after baseline assessment);

- Episodes of (retrospective medical file data, all between baseline assessment and death):

o Symptomatic hypertension,

o symptomatic hypotension,

o symptomatic hypoglycaemia

o symptomatic hyperglycaemia,

o thrombo-embolic complications,

o bleeding events

Other study parameters

- Health economic analysis and cost-effectiveness ratio of:

o Patients and relatives at baseline and four weeks after baseline assessment (self-reported HRQoL, capabilities, resource use, employment and patient activities/informal care needs from patients based on the EQ-5D-5L, ICECAP-SCM or CPM, HEQ, partial IVICQ, CIIQ)

o Intervention: development and training costs, operational costs (including time spent on discussing medication alerts with the pharmacist and patient/relative)

For the subgroup of patients who will be included in the Netherlands extra endpoints will be measured:

- Health economic analysis and cost-effectiveness ratio of patients every four weeks after baseline assessment (self-reported HRQoL, capabilities, resource use, employment and patient activities/informal care needs from patients based on the EQ-5D-5L, ICECAP-SCM, HEQ)

Study description

Background summary

Adequate use of medication is a crucial aspect of care for patients in the last phase of life. Many patients experience multiple distressing symptoms, especially in the last weeks of life. Inadequate control of symptoms has been documented in patients with advanced and end-stage disease and has a huge impact on patients* quality of life. At the same time, many patients continue to receive unnecessary medication in the last phase of life, without beneficial outcomes. Scientific evidence on the safety of stopping medications is scarce. We have designed a study to evaluate the effect of a personalized medication advice on the quality of life in the last phase of life. The medication advice, which will contain alerts, is given by using a Clinical Decision Support System (CDSS). This guidance is based on a broad set of clinical decision rules using knowledge about medication interactions, individual results of blood tests and patient characteristics. The alerts will be adapted for patients who are in the last phase of their lives, i.e. with a life expectancy of maximal 6 months. The aim is to see whether a personalized medication advice contributes to the quality of life in patients in the last phase of life.

Study objective

The objective is to examine whether the use of CDSS-OPTIMED, a personalized medication advice to attending physicians of patients in the last phase of life, contributes to patients* quality of life.

Study design

The iLIVE medication optimisation study will be performed in three countries: the Netherlands, Sweden and Switzerland. In total, there are 10 different sites (clusters) (5 from the Netherlands, 3 from Switzerland, and 3 from Sweden). We will examine the effect of a personalized medication advice provided by a CDSS to support physicians in adequately prescribing and deprescribing medication, based on available evidence, pharmacological/medical knowledge and on known patient*s symptom load. The effect of this personalized advice will be evaluated in a before-after study, with the different study sites being the clusters. The study sites will switch from control to intervention after approximately 12 to 18 months. All study sites will start as control sites, where care is provided as usual. After approximately 12 to18 months the study sites will switch from control to intervention. There will be 2 observation periods in 122 weeks. Within two weeks before and ultimately two weeks after

starting the crossover, researchers will visit the study sites. Physicians will then be trained by the researchers to use the tool in a 2 hour session or by a trainingsvideo. Both the training and the video includes advice on how to communicate about medication management at the end of life with patients and their families. Within these four weeks of training there will be a period of non-inclusion.
The attending physicians in the intervention group will receive a medication review within 1 week after inclusion. The medication review will be sent to the physician*s email address. The physician is free to follow or ignore the advice in the alert.

The iLIVE medication optimization study is embedded in a broader international project, the iLIVE cohort study, which involves a prospective cohort study in 11 countries. Patients with a maximum estimated life expectancy of six months and their relatives are included and they will be followed up until patients* death, if that may occur before the end of the data collection, to measure their concerns, expectations and preferences in the last phase of life.

Intervention

We will evaluate the effect of a personalized medication advice on adequate medication management in patients in the last phase of life provided by an CDSS (CDSS-OPTIMED). An CDSS is a software program that provides the physician with a personalized alert on whether to consider stopping or starting medication for a specific patient. The CDSS was initially developed to optimize medication surveillance in older patients using numerous medication. In this study, we will evaluate a specific set of rules for patients in the last phase of life, which we refer to as CDSS-OPTIMED. This provides alerts on medication that may be stopped in patients who are in the last phase of their lives, i.e. with a life expectancy of maximal 6 months, and on medication that may be prescribed for symptom control. To make the latter possible, information on patients* symptom load as assessed with the ESAS questionnaire is added to the original CDSS system.
All rules are based on evidence from scientific literature and are very extensively described in several literature reviews. The rules that will be specifically added to the CDSS-OPTIMED are validated by a currently ongoing Delphi study among an international panel of around 89 experts.
In order to guarantee adequate use of the CDSS-OPTIMED and of communication with the patient and relatives about the alerts in each site, physicians will be trained. In this training the use of the CDSS-OPTIMED will be discussed and advices on how to communicate about medication optimisation with patients and their families are given.

Study burden and risks

The iLIVE project involves human beings, in particular patients in the last

phase of life and their relatives. Further, the study collects and processes personal data, through questionnaires and interviews and through reviews of patients* medical files.
Use of the CDSS-OPTIMED is expected to result in more well-considered prescription of medication, which may involve decreased use of potentially inappropriate medication and increased use of medication to control symptoms. Improved medication management is hypothesized to improve patients* quality of life and reduce the burden of potentially inappropriate medications. The CDSS-OPTIMED is based on available evidence and does not involve experimental treatment or experimental medication management strategies. The only envisaged potential risks are therefore the already known side effects of (deprescribing) specific types of medication. The alerts from the CDSS-OPTIMED are based on guidelines, a thorough literature search and a currently ongiong Delphi study among international experts in palliative care and in cardiology and diabetology.
The study population concerns vulnerable people who often experience fluctuating symptoms across their disease trajectory. Although this can cause varying levels of frailty, patients in the last phase of life and their caregivers have repeatedly been reported to be willing to participate in research studies, even when they are close to death. Ethical concerns around patient participation in end-of-life care research are thus not always justified: patients and their caregivers may feel that taking part in research contributes to their feeling of being worth living and their satisfaction with life. They may feel that they are actively participating in their health care,or they wish to contribute to changing practice, knowing that they will not experience such change themselves.
Nevertheless, we explicitly acknowledge the potential vulnerability of patients in the last phase of life and their relatives and the risk of overburdening or stigmatization. Study participants will as a matter of principle be approached as people who are in principle fully capable of participating in research and whose experiences and concerns are of the utmost importance for caregivers to learn from. If patients feel burdened by their participation, they are encouraged to indicate that on the questionnaire or to the researcher. Patients are also encouraged to discuss their issues with relatives or a healthcare professional.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patient:
1. Patient is 18 years or over and provides informed consent to participate.
2. The patient is aware that recovering from his/her disease is unlikely, as assessed by the attending physician.
3. The patient agrees to participate in the iLIVE cohort study.
4. The attending physician would not be surprised if the patient were to die within 6 months (*Surprise question*).
5. If the physician is uncertain about the surprise question, the patient is eligible if presenting with at least one SPICT indicator.

Relative:
Relatives of included patients are asked to participate if they are:
1. 18 years or over and provide informed consent to participate; aware that it is unlikely that the patient will recover from his/her disease;
2. capable of filling in a questionnaire in the country*s main language or in English.

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 attending physician makes the decision that the patient should not be included in the study due to e.g. illness burden, fast deterioration or imminent death, lack of trusting relationship with the physician.

Relative:
Relatives are not eligible if they are incapable of filling in a questionnaire in the country*s main language or in English. No more than one relative per patient will be included.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-04-2021
Enrollment:	110
Type:	Actual

Medical products/devices used

Generic name:	Clinical Rules Reporter (CRR) (for this study renamed as CDSS-OPTIMED)
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	17-07-2020
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	04-03-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	03-08-2023
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL72473.078.20