Morphine for palliative treatment of refractory dyspnea in patients with advanced COPD: benefits and respiratory adverse effects

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Primary objectives are:1.1) to study the effect of oral administration of morphine SR on health-related quality of life; 1.2) to explore whether morphine SR leads to respiratory adverse effects in patients with advanced COPD. Secondary objectives...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Interventional

Summary

ID

NL-OMON47485

Source
ToetsingOnline

Brief title
MORDYC

Condition

- Bronchial disorders (excl neoplasms)

Synonym
COPD; Chronic Obstructive Pulmonary Disease

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht

Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: COPD, Dyspnea, Morphine, Opioids

Outcome measures

Primary outcome

- Health-related quality of life;

- Respiratory parameters.

Secondary outcome

- Functional capacity;

- The relationship between response to morphine and severity of dyspnea and

descriptors of breathlessness will be explored;

- Cost-effectiveness.

Study description

Background summary

Dyspnea is the most reported symptom of patients with advanced Chronic Obstructive Pulmonary Disease (COPD) and is undertreated. Morphine is an effective treatment for dyspnea and is recommended in current guidelines, but questions about use of morphine in patients with COPD remain. For example, the effect on health-related quality of life and functional capacity remains unknown. Moreover, in one-third of the patients oral sustained release morphine (morphine SR) does not relieve dyspnea and to date it remains unknown whether severity of dyspnea and descriptors of breathlessness may predict a response to morphine. Finally, cost-effectiveness is unknown. Therefore, prescription of morphine to patients with advanced COPD and severe dyspnea is limited.

Study objective

Primary objectives are:
1.1) to study the effect of oral administration of morphine SR on health-related quality of life;

1.2) to explore whether morphine SR leads to respiratory adverse effects in patients with advanced COPD.

Secondary objectives are:
2.1) to study the effect on functional capacity;
2.2) to explore whether description and severity of breathlessness are related with a clinically relevant response to morphine;
2.3) to analyse the cost-effectives of morphine SR in patients with advanced COPD.

Study design

double-blind placebo controlled intervention study, followed by a cohortstudy.

Intervention

Patients will be randomized in an intervention group receiving morphine SR and a control group receiving placebo. At the end of the intervention period, the patients can choose to continue the morphine treatment.

Study burden and risks

Participants will be asked to complete a baseline and outcome-assessment (two site visits between 2 and 3 hours); diary cards (four weeks); two home visits (1 hour each) and two phone calls (0.5 hour each) within four weeks. They will be asked to complete questionnaires and perform 4 times a Timed *Up & Go* test. Two arterial blood gases will be drawn. Lung function will be measured. Furthermore, overnight oximetry will be performed twice at their own homes. Finally, a package of several questionnaires will be sent to their home address 4, 8 and 12 weeks after completion of the intervention period. They will be asked to complete these questionnaires.
Patients may experience adverse affects of morphine like nausea, constipation, and drowsiness. Adverse affects will be monitored closely and will be minimized because the maximum dosage of morphine will be 30mg per day. Patients will receive laxatives to prevent constipation and anti-emetics to prevent nausea.

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

* diagnosis of COPD according to the current Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease (GOLD);;* optimal pharmacological treatment including treatment with a combination of a long-acting muscarinic antagonist and an ultra-long-acting *-agonist; ;* Grade 2, 3 or 4 dyspnea on the mMRC; ;* optimal non-pharmacological treatment defined as completed a comprehensive pulmonary rehabilitation program

Exclusion criteria

* history of substance misuse;
* exacerbation of COPD within two weeks of study enrolment;
* waiting list for lung transplantation;
* pregnant or childbearing potential not using contraception;
* renal failure (creatinine clearance <15mL/min);
* age under 18
* not being able to read or fill in the questionnaires or diary
* allergy for morphine or its excipients
* concomitant use of irreversible MAO blockers
* use of opioids
* history of convulsions

* head injury
* intestinal obstruction
* gastroparesis
* liver disease

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-11-2016
Enrollment:	124
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	morphine sustained release
Generic name:	morphine sustained release
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	15-01-2015
Application type:	First submission

Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	02-04-2015
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	19-11-2015
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	17-12-2015
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	28-11-2016
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	05-12-2016
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	04-07-2017
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	12-07-2017
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
EudraCT	EUCTR2014-004899-35-NL
ClinicalTrials.gov	NCT02429050
CCMO	NL51905.068.14