The blood circulation during end-of-life. Observation of the blood circulation of hospice patients before and after the diagnosis of dying: a pilot study.

Published: 11-09-2012
Last updated: 26-04-2024

The first objective of this pilot is to determine the feasibility of the measurements of the blood circulation in patients during the last phase of life. The second objective is to survey the quality of the blood circulation, particularly the...

Ethical review	Not approved
Status	Will not start
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON36876

Source
ToetsingOnline

Brief title
The blood circulation during end-of-life.

Condition

- Other condition

Synonym
Patients during end-of-life

Health condition

Patiënten gedurende de laatste fase van het leven

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: blood circulation, Diagnosis dying

Outcome measures

Primary outcome

1.The feasibility of the pilot (to determine if the study could be done on larger scale), determined on three criteria: a. possible practical problems of measuring, b. the willingness to participate the study, c. reactions to the measurements of patients and their relatives.

2.An inventory of the course of the blood circulation, measured by four non-invasive measurement instruments, before and after the recognition of the dying phase.

Secondary outcome

The relationship of the course of the blood circulation (the pulsatory volume, the heart rate, blood pressure, cardiac output, systemic vascular resistance, peripheral perfusion, peripheral oxygenation and perfusion of the microcirculation) measured through four non-invasive measurement instruments with clinical signs of the approached death to patients with a life expectancy of only days.

Study description

Background summary

If the death of a patient is unavoidable within a short period (a few days), further medical interference with the goal to reach life extension is useless and potentially harmful. In practice this so-called dying phase frequently is recognized late or is even not recognized. One of the reasons for this shortcoming is that there is a lack of an objective parameter that could determine this dying phase. An important reason for this is that there is hardly any knowledge of the physical process of dying.
A core system of the physiology of the human body is the blood circulation. During the last years investigation, non-invasive, of the blood circulation is done frequently in severe ill intensive care patients. It is proven that particularly the determination of the microcirculation can give valuable information about the prognosis and clinical outcomes of patients.

Study objective

The first objective of this pilot is to determine the feasibility of the measurements of the blood circulation in patients during the last phase of life. The second objective is to survey the quality of the blood circulation, particularly the microcirculation, during the last phase of life. Dependent on the outcomes of the pilot further investigation will be done to investigate the value of measuring the blood circulation in order to determine the dying phase.

Study design

The pilot will take place during two weeks. All patients who stay at hospice Cadenza at the start or who will be admitted to the hospice during the first week of the pilot and where the presumption is that they are not dying (not *in the dying phase*) will be asked to participate in the pilot. After inclusion the bloodcirculation will be measured one time (measurement A). In all patients where the presumption of the physicians and nurses of the hospice during the two weeks of the pilot is that they will die within a few days the measurement will be repeated (measurement B). If the concerned patient will not die within the presumed few days but, during the pilot, the presumption is still that the patient will die within a few days the measurement will be repeated again. Measurement B will be done at most three times. In total, measurement A and B, the measurement of the blood circulation will be done four times.
The blood circulation will be measured by four non-invasive measurement instruments. With this, parameters of the macrocirculation (such as the pulse rate and the blood pressure) and the microcirculation (oxygenation and perfusion) will be determined. Beside, more general measurements, such as the

fluid intake of the patient and the determination of the Karnofsky score, will be measured.

Study burden and risks

Because the determination of the blood circulation (micro- and macirculation) will be done by means of non-invasive measurements the physical load is minimally. However, the approaching death is accompanied with many distressed feelings by which participation to the pilot could produce an emotional reaction to the included patients and their relatives. We will verify this carefully.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

's-Gravendijkwal 230
Rotterdam 3015 CE
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

's-Gravendijkwal 230
Rotterdam 3015 CE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Estimated life expectancy of three months or less
2. Age >= 18 years

Exclusion criteria

1. Insufficient understanding of the Dutch language
2. Functional disorders (for example severe dementia or delirium)
3. Great oral cavity defect as a result of a (treatment of) malignancy

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	25
Type:	Anticipated

Ethics review

Not approved

Date:	11-09-2012
Application type:	First submission
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	NL41525.078.12