Effect of incentive spirometry in prevention of acute chest syndrome during painful crisis in adult sickle cell patients

Published: 04-03-2010
Last updated: 02-05-2024

To evaluate the efficacy of incentive spirometry on the incidence of ACS in adult sickle cell patients admitted with a vaso-occlusive painful crisis.

Ethical review	Approved WMO
Status	Pending
Health condition type	Haemoglobinopathies
Study type	Interventional

Summary

ID

NL-OMON34975

Source
ToetsingOnline

Brief title
Spirometry and Acute Chest Syndrome

Condition

- Haemoglobinopathies

Synonym
sickle cell anemia, sickling of the lungs

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: acute chest syndrome, sickle cell disease, spirometry

Outcome measures

Primary outcome

1. To evaluate the efficacy of incentive spirometry in primary prevention of ACS in adult sickle cell patients during painful crisis.

Secondary outcome

1. To relate the efficacy of incentive spirometry to plasma levels of phospholipase A2 and serum levels of procalcitonine.

2. To evaluate whether plasma sPLA2 levels may be helpful to stratify patients in high and low risk groups and to evaluate the value of incentive spirometry in these groups to prevent ACS.

3. To evaluate whether serum procalcitonine may stratify patients with an ACS related to an infectious and non-infectious pathogenesis and to evaluate the value of incentive spirometry to prevent ACS.

4. To identify the micro bacterial organisms responsible for the development of an acute chest syndrome and to relate this with the procalcitonin plasma levels.

Study description

Background summary

One of the most severe complications during vaso-occlusive painful crisis is the acute chest syndrome (ACS), ACS is defined as the presence of a new pulmonary infiltrate (on chest X-ray) in combination with clinical symptoms such as fever or respiratory symptoms in a patient with SCD. Incentive spirometry has been demonstrated to be effective as primary prevention of the development of ACS in children admitted with a vaso-occlusive painful crisis. However, the effect of incentive spirometry in prevention of ACS in adult sickle cell patients during painful crisis has not been studied so far. Therefore, the aim of our study is to evaluate the efficacy of incentive spirometry on the incidence of ACS in adult sickle cell patients admitted with a vaso-occlusive painful crisis.

Study objective

To evaluate the efficacy of incentive spirometry on the incidence of ACS in adult sickle cell patients admitted with a vaso-occlusive painful crisis.

Study design

A multicentre randomized controlled clinical trial, studying the effect of incentive spirometry on the incidence of ACS in comparison with standard care in adult sickle cell patients admitted with a vaso-occlusive painful crisis.

Intervention

Patients in the study group will be educated in the use of the spirometer (Respiflo*FS, Kendall) and the study protocol by the investigator. During admission patients have to inhale10 times through the spirometer every 2 hours (between 8 a.m. and 10 p.m.) until at least 24 hours after the pain has subsided. If awake, patients may use the spirometry also between 10 p.m. and 8 a.m. Patients are asked to register every time they inhale through the spirometer and pain scores will be assessed (Visual Analog Scores).

Study burden and risks

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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

High performance liquid chromatography confirmed diagnosis of HbSS, HbSC, HbSB0- or HbSB+-thalassemia genotypes.
Written informed consent by the patient.
Thoracic or back pain above the diaphragm.
Hospital admission due to vaso-occlusive painful crisis.

Exclusion criteria

Blood transfusion in the preceding three months
Diagnosis of Acute Chest Syndrome at presentation

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2010
Enrollment:	70
Type:	Anticipated

Medical products/devices used

Generic name:	Respiratory Exerciser
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL31253.018.10