Management of childhood empyema: is there any abnormal lung-function after surgical intervention?

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MAIN QUESTIONIs there any difference in the lungfunction of those people, who have undergone surgical intervention since 1985 in relation to a childhood empyema, compared to the refence population?Which determinants caused a degraded pulmonary...

Ethical review	Approved WMO
Status	Pending
Health condition type	Pleural disorders
Study type	Observational non invasive

Summary

ID

NL-OMON30020

Source
ToetsingOnline

Brief title
Lung-function after childhood empyema with surgical intervention

Condition

- Pleural disorders

Synonym
lung empyema, pleural empyema

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: collectebusfondsen

Intervention

Keyword: (Pleural) Empyema, Childhood, Lung-function, Surgery/surgical intervention

Outcome measures

Primary outcome

Primary study parameters of the pulmonary function test:

*Total lung capacity (TLC), FEV1/VC

Primary study parameter of the exersize test:

*VO2 max.

Secondary outcome

Secundary study parameters of the pulmonary function test:

*Forced vital capacity (FVC), FEV1, Maximal mid-expiratory flow (MMEF25*75%),

Residual volume (RV), diffusion capacity.

Secundary study parameters of the exersize test:

*heart frequenty max. (HF max.), max. exercise ventilation/max. voluntary

ventilation, max. tidal volume/inspiratorycapacity (Vt max/IC), O2 pulse, SO2,

respiratory quotiënt (VCO2/VO2).

Study description

Background summary

There is no consensus about the right treatment in childhood empyemas, which is mostly a complication of bacterial pneumonia. Lots of studies have been done to investigate the short term results of different treatments. Parameters were: length of hospital stay, duration of symptoms, duration of oxygen supply, IC admission, no. of drains etc. Because of the results, which aren't similar at all, and the very low incidence of this childhood disease, there not enough evidence to choose the right treatment. Long term results haven't been investigated as well as the short term results, especially the long term results of surgical intervention. This may be very important, because of the low mortality of this disease, which means more long term complications, and the lack of evidence in relation to the right treatment in short term studies. This study will give us an overview of the lungfunctions of those people who have had surgical treatment in relation to a childhood empyema in the last twenty years.

Study objective

MAIN QUESTION

Is there any difference in the lungfunction of those people, who have undergone surgical intervention since 1985 in relation to a childhood empyema, compared to the refence population?

Which determinants caused a degraded pulmonary function?

Study design

It's a descriptive study to the lungfunction of those people, who were treated by surgery for childhood empyema. They will be called upon to participate in a pulmonary function test and an exercise test.

The study design has been created in such a way that it serves as a pilot-study and eventually as part of a greater research study (i.e. a longitudinal prospective study and/or a retrospective comparative study).

Study burden and risks

This study has a very low risk indication.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

The empyemas must suffice the next criteria: 'febrile illness with pulmonary dysfunction', 'accumulation of fluid in the pleural space on X-thorax or ultrasound' and 'purulent fluid in pleural space or signs of loculations on X-thorax or ultrasound/ WBC count * 15.000/*l.* Patients have undergone video assited thorocoscopic surgery, decortication or thoracotomy.

Exclusion criteria

Phase 1 empyemas; empyemas caused by trauma, surgery (other than interventional

surgery) or tbc; mental retardation, age <6 years or chromosomal disease (cannot do pulmonary function testing); prematurity (<32 weeks), other lung diseases, such as cystic fibrosis, lung resections and asthma.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	05-01-2006
Enrollment:	60
Type:	Anticipated

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	NL11860.029.06