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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25528

Source
Nationaal Trial Register

Brief title
Lung-function after childhood empyema with surgical intervention

Health condition

All the people, who have had an childhood empyema since 1985, will be included. The patients must have been admitted in the VU hospital or AMC hospital, which are both in Amsterdam, and they must have had a surgical operation, such as video assisted thoracoscopic surgery, decortication or thoracotomy. At the moment of follow up they have to be 6 years or older.

Sponsors and support

Primary sponsor: VU medical centre (Amsterdam); see scientific contact
Source(s) of monetary or material Support: None, till now

We will search for external funds, like the asthma fund.

Intervention

Outcome measures

Primary outcome

Primary study parameters of the pulmonary function test:

1. Total lung capacity (TLC);

2. FEV1/VC;

Primary study parameter of the exersize test:

3. VO2 max.

Secondary outcome

Secundary study parameters of the pulmonary function test:

1. Forced vital capacity (FVC);

2. FEV1;

3. Maximal mid-expiratory flow (MMEF25-75%);

4. Residual volume (RV);

5. Diffusion capacity.

Secundary study parameters of the exersize test:

6. Heart frequenty max. (HF max.);

7. Max. exercise ventilation/max. voluntary ventilation;

8. Max. tidal volume/inspiratorycapacity (Vt max/IC);

9. O2 pulse;

10. SO2;

11. 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

We expect that there will be a restrictive condition in the first place. After a longer period there may be an obstructive condition, due to the original infection. We expect that the leucocyte count of the pleural fluid, the number of loculations on ultrasound or CT scan and the per/postoperative complications at admission will predict a reduced pulmonary function.

Study design

N/A

Intervention

1 pulmonary function test and 1 excersice taking 4-5 hours of time.

Contacts

Public
Academic Medical Center (AMC), Emma Children's Hospital and VU University Medical Center, Department of Pediatric Surgery (9d32),
P.O. Box 22660
H.A. Heij
Meibergdreef 9

Amsterdam 1100 DD
The Netherlands
+31 (0)20 5665693
Scientific
Academic Medical Center (AMC), Emma Children's Hospital and VU University Medical Center, Department of Pediatric Surgery (9d32),
P.O. Box 22660
H.A. Heij
Meibergdreef 9
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5665693

Eligibility criteria

Inclusion criteria

1. The childhood empyemas treated by surgery 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/microl;

2. Patients have undergone video assited thorocoscopic surgery, decortication or thoracotomy.

Exclusion criteria

1. Phase 1 empyemas;

2. Empyemas caused by trauma, surgery (other than interventional surgery) or tbc;

3. Mental retardation, age <6 years or chromosomal disease (cannot do pulmonary function testing);

4. Prematurity (<32 weeks), other lung diseases, such as cystic fibrosis, lung resections and asthma.

Study design

Design

Study type:	Interventional
Intervention model:	Factorial
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2006
Enrollment:	60
Type:	Actual

Ethics review

Positive opinion

Date:	08-06-2006
Application type:	First submission

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
NTR-new	NL640

Register	ID
NTR-old	NTR700
Other	METC : 2006/110
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A