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

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Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25528

Bron
NTR

Verkorte titel
Lung-function after childhood empyema with surgical intervention

Aandoening

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.

Ondersteuning

Primaire sponsor: VU medical centre (Amsterdam); see scientific contact
Overige ondersteuning: None, till now

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

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Factorieel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-07-2006
Aantal proefpersonen:	60
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	08-06-2006
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL640
NTR-old	NTR700
Ander register	METC : 2006/110
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A