Chloor Asthma Syndroom: an Evaluation

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The study objectives are to measure the impact of swimming in chlorinated water on the upper and lower airways of children with and without *doctors diagnosed asthma* by means of the following methods: 1.Tympanometry after otoscopy 2.Airway…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Middle ear disorders (excl congenital)
Study type	Observational non invasive

Summary

ID

NL-OMON33812

Source
ToetsingOnline

Brief title
CHASE

Condition

- Middle ear disorders (excl congenital)
- Exposures, chemical injuries and poisoning
- Bronchial disorders (excl neoplasms)

Synonym
acute otitis media/otitis, chloorasthma/ idem

Research involving
Human

Sponsors and support

Primary sponsor: Spaarne Ziekenhuis
Source(s) of monetary or material Support: privé fonds van kinderartsen Spaarneziekenhuis.

Intervention

Keyword: asthma, children, otitis, swimmingpool

Outcome measures

Primary outcome

group A:

1.peak pressure (kPa) /compliance (ml/kPa)

2.airway resistance kPa/l.s

3.Association of occurrence of otitis with change peak pressure/compliance

before and after swimming

4.Association of occurrence of asthma with change in airway resistance before

and after swimming

Group B:

1.NO in expiration air (ppb)

2.FEV1 (l) MEF 50% (L/s)

3.Association of occurrence of asthma with change FENO before and after

swimming.

4.Association of occurrence of asthma with change FEV1 and MEF 50% before and

after swimming

Secondary outcome

group A:

1.Association between peak pressure and compliance with occurrence of

otitis

2.Change of airway resistance before and after swimming

Group B:

1.Change of FENO before and after swimming

2.Change of FEV1 and MEF 50% before and after swimming

Study description

Background summary

In the Western world in the previous decades a strong increase of asthma has been observed. Given the velocity of this increase it can postulated that genetic factors alone are insufficient to explain this phenomenon. It is reasonable to search for environment factors, which can give an explanation for this increase. Young children learn * considering our climate- swim in chlorinated swimming pools . This belongs meanwhile to our 'life-style'. During these instuctions the airways of these children are exposed to chlorinated hydrogen molecules. Last years some studies showed an association between lung damage and asthma as a result of inhaled chlorine connections during the swimming pool visit. Concerning middle ear inflammation this association less is clear. The hypothesis is that the developing airways of the young child are themselves more sensitive for damage as a result of toxins i.e. chlorinated air inhalation.

Study objective

The study objectives are to measure the impact of swimming in chlorinated water on the upper and lower airways of children with and without *doctors diagnosed asthma* by means of the following methods:

1.Tympanometry after otoscopy
2.Airway resistance measurements
3.Measurement of NO in the exhaled air
4.Expiratory flow-volume measurements

Study design

The parents of children who take part in the swimming instructions are informed by letter of the studies. They are requested to complete the CHASE questionnaire (modified Los Angeles Health screening survey) and send this to the research worker. In association with the management of the swimming pool institution the children are included for the study after informed consent is obtained.

Study A:
Methods:
- Study design: descriptive open cohort study
- Otoscopy: evaluation of the tympanum on aspect of ear drum and presence of fluid
- Tympanometrie: peak pressure/compliance measurement with tympanometer of
Madson ®
- Airway resistance: by means of a non invasive interrupter technique with
MicroRint ®

Measurements are performed before and after the swimming instruction .
Three months after the measurements the parents will be contacted by telephone. Questions regarding the occurrence of ear inflammation in the previous research period will be asked.

Study B:
Methods:
- Study design: descriptive open cohort study
- Measurement of the Fractional Exhaled Nitric Oxide (FENO) with
Nioxmino ®
- Measurement of expiratory volume flow curve with meter of PT Medical ® Measurements are performed
before and after the swimming instruction
.
After a period of three months the measurements are repeated and the (short) questionnaire CHASE will be completed

Study burden and risks

The used measurements are non invasive and are common in our paediatric practice.
There is no medical risk for the participating child.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

healthy children and children with 'docters diagnosed asthma' aged 5 up to 8 years included who participate in the swimming lessons in a chlorinated swimmingpool.

Exclusion criteria

study A: recent paracenthesis (< 0.5 jaar)
anatomical abnormalities of the upper airway
nasal decongestatory and or bronchodilatory medication
study B:unstable astma with beta2 medication <8 hrs before measurement.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-12-2010
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	11-02-2010
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	NL20876.029.08