First immunization of premature infants born before 33 weeks of gestation; safe at home or is cardiorespiratory monitoring in the hospital necessary?

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The purpose of this study is to determine whether the first immunization causes cardiorespiratory events in premature born children that have already been discharged from the hospital.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON41573

Source
ToetsingOnline

Brief title
Cardiorespiratory disturbances after 1st vaccination in premature infants

Condition

- Other condition

Synonym
cardiorespiratory incidents post-immunization, safety of immunization

Health condition

verstoringen van vitale functies na reguliere vaccinatie

Research involving

Human

Sponsors and support

Primary sponsor: Medisch Centrum Alkmaar
Source(s) of monetary or material Support: geen vergoeding.

Intervention

Keyword: cardiorespiratory problems, immunization, premature, safety

Outcome measures

Primary outcome

Number and characteristics of the following cardiorespiratory events:

- apnea

- bradycardia

- cyanosis

definitions

- apnea = isolated respiratory pause >= 20 seconds or respiratory pause > 15

seconds combined with a heart rate < 80 beats/minute

during at least 5 seconds.

- bradycardia = hearts rate < 80 beats/minute during at least >= 20 seconds.

- cyanosis = transcutaneous oxygensaturation < 86% during > 15 seconds.

Secondary outcome

- bodytemperature

- local skin reaction

- changed nutritional pattern

- changed sleep pattern

- need for analgesia

Study description

Background summary

Current guidelines advise to administer the first immunization to preterm infants at the age of 2 months as protection against infectious diseases is important for these vulnerable infants. However, it is uncertain whether immunization at such a young postconceptional age is safe or not. Previous studies indicate that these infants are at increased risk of post-immunization cardiorespiratory disturbances. Therefore cardiorespiratory monitoring after immunization may be necessary.
Extremely premature born infants usually still reside in the neonatal ward at the age of 2 months, and consequently cardiorespiratory monitoring after the first immunization can easily be applied. However, less extremely premature born infants have often already left the hospital by the time they have to receive their first immunization. In them, the need for cardiorespiratory monitoring will lead to re-admission to the hospital. It is important to know whether cardiorespiratory monitoring in these recently discharged ex-premature children is really needed.

In a previous study we observed only benign cardiorespiratory events following the first immunization in premature born infants who had already left the hospital before the first immunization. This led us to conclude that immunization without cardiorespiratory monitoring appears to be safe in these infants. However, limitations of the first study were the limited sample size and the lack of a control group. In order to provide stronger evidence for the suggested strategy (immunization at home without cardiorespiratory monitoring) we want to continue our research in a next study. In the proposed study we focus on the causal relation between immunization and the observed cardiorespiratory events

Study objective

The purpose of this study is to determine whether the first immunization causes cardiorespiratory events in premature born children that have already been discharged from the hospital.

Study design

Prospective observational cohortstudy.

After informed consent of the parents is obtained, children are re-admitted to

the our hospital at the uncorrected age of 2 months the afternoon of the day before the vaccination is given. On the day of admission the children are cardiorespiratory monitoring starts. The vaccine is administered at 09.00hours on day 2, and monitoring then continued for 24 hours. Immunization takes place according to the rules of the national vaccination program. All patients receive a pneumococcal conjugate vaccine (Synflorix) and a combination vaccine for diphtheria (D), acellular pertussis (aP), Tetanus (T), Polio (P), Haemophilus influenzae B (Hib) and Hepatitis B (infanrix hexa). Disturbances in cardio-respiratory parameters will be described using a standardized form. An apnea is defined as an isolated respiratory arrest of >= 20 seconds or an apnea of> 15 seconds with a heart rate <80 beats per minute for 5 seconds (Stein Schneider). A bradycardia is defined as a heart rate <80 beats per min for >= 20 seconds. Finally, desaturation refers to a transcutanous measured oxygen saturation <86% for > 15seconds. All these values will be noted during an incident and regardless of that every three hours. Furthermore, if an incident occurs the neonatal event registration will be printed out, so sequence of events can be determined. Finally, every three hours adverse reactions such as local skin reactions, temperature instability, gastrointestinal complaints, sleep disturbances and need for analgesics are noted following the standardised observation lists.

Study burden and risks

Extra burden consists of an extra night observation in the hospital (the night before the immunization).
No increased risk.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

children born prematurely (gestational age <33 wks)
discharged from the hospital in clinically stable condition at the age suitable for administration of
1st DaKTP-Hib-HepB-Pneu immunization (=postnatal age of 2 months).

Exclusion criteria

No approval of parent.
Need for respiratory support or tubefeeding at home.
Any known congenital or acquired medical condition potentially affecting cardiorespiratory stability.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-01-2015
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	05-03-2013
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	02-02-2016
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)

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	NL35641.094.12