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Does drinking formula milk reduce the pain that infants experience during vaccination?

Submission date
12/11/2015

Recruitment status
No longer recruiting

Registration date
06/12/2015

Overall study status
Completed

Last Edited
30/05/2017

Condition category
Signs and Symptoms

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Vaccinations are one of the best ways to protect babies from serious childhood diseases. The 5-in-1 vaccine (also known as the DTaP/IPV/Hib vaccine) and the pneumococcal vaccine are among the most important vaccinations a child will have in their first few months of life, protecting against illnesses which are potentially disabling or even fatal. In many cases, children can find the vaccination experience painful and unpleasant, which can be extremely distressing to their parents. Previous studies have found that breastfeeding a baby or feeding them sugar water before, during and after their vaccination can help to soothe them, and appear to reduce pain. Currently, there is no real evidence whether this works with baby formula. Many parents choose to feed their baby using formula, and so these children are not able to receive the soothing effects of breastfeeding in their vaccinations. The aim of this study is to find out whether feeding babies formula during their routine vaccinations can help to lower pain levels and stop them from crying.

Who can participate?
Healthy, formula fed babies who are between 4-10 weeks old at the time of their vaccinations.

What does the study involve?
Participants are placed into one of two groups. Those in the first group are given formula milk to drink from 2 minutes before their vaccination until afterwards, for as long as they like. Those in the second group are not given anything to put in their mouths. Children in both groups are held and comforted by their parents during their vaccinations. Throughout the study, the children in both groups are watched to see if they are showing any signs of being in pain, and if they cry, for how long. The day after the vaccinations, the parents of the children who were given formula are contacted in order to find out if they have refused their formula or if their children needed pain relief (paracetamol) at any point.

What are the possible benefits and risks of participating?
Participants in the feeding group may experience less pain during their vaccination. There is a small risk that children in the feeding group may choke on the formula during the vaccination or refuse the formula after the vaccination.

Where is the study run from?
University Medical Centre Groningen (Netherlands)

When is the study starting and how long is it expected to run for?
September 2014 to December 2014

Who is funding the study?
The Public Child Healthcare organization of Groningen (Netherlands)

Who is the main contact?
Mrs Netty Bos-Veneman

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Formula feeding as pain reducing method during vaccination

Study objectives
Formula feeding during vaccination reduces pain experienced by infants.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Medical Ethical Committee of the University Hospital of Groningen (Netherlands) has exempted this study from medical ethical evaluation (METc UMCG 2014.274) because the intervention used (formula feeding) is familiar to the child, not invasive, most probably without clinically relevant side effects. Thereby pain was only measured once by observation.

Study design
Single-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details below to request a client information sheet.

Health condition(s) or problem(s) studied
Pain experienced by infants during vaccination

Interventions
Interventions as of 30/05/2017:
Participants are randomised to one of two groups using sealed, opaque envelopes stratified by sex.

Intervention group: Infant formula feeding is given at the moment of the vaccination. All parents bring formula feed and bottles from home. Infants receive pain reduction through sitting in a half supine position on the lap of the parent, who comforts the infant in their own way, for example by talking and cradling. The drinking of formula milk starts two minutes before the first injection and continues during and after vaccination as long as the infant likes.

Control group: Infants are not allowed to have anything in their mouths. Infants have to be relaxed just before the first vaccination is given. They receive pain reduction through sitting in half supine position on the lap of the parent, who comforts the infant in their own way, for example by talking and cradling.

The NIPS and FLACC lists are scored during two periods of 15 seconds, the first beginning at the moment of injection of the pneumococcal vaccination and the second starting 60 seconds after injection.

Original interventions:
All infants receive pain reduction through sitting in half supine position on the lap of their

parent, who comforted their infant in their own way, for example by talking and cradling. Infants in the study group drink formula milk for two minutes before they receive vaccination, and they continue to drink during and after the vaccination as long as they like. Infants in the comparator group do not have anything in their mouths during this time. Infants in both groups are observed throughout the vaccinations and afterwards so that their level of pain can be predicted i.e. from crying, movement, facial expression etc.

Intervention Type
Other

Primary outcome measure
1. Pain is measured using the Neonatal Infant Pain Scale (NIPS) and Face, Legs, Activity, Cry, and Consolability (FLACC) during two periods of fifteen seconds beginning at the moment of injection and 60 seconds after injection
2. Cry duration is assessed by measuring the duration of high-frequency and rhythmic vocal expression of the infant between the moment of injection until a period of silence of at least five seconds.

Secondary outcome measures
1. Choking in the formula feeding is recorded continually through the study
2. Number of formula feedings their infant had refused after vaccination is recorded by interviewing parents the day after the vaccination
3. Whether the infant had been given acetaminophen (paracetamol) is recorded by interviewing parents the day after the vaccination

Overall study start date
01/09/2014

Completion date
15/12/2014

Eligibility

Key inclusion criteria
1. Aged between 4-10 weeks old when they received their first DTaP-IPV-HepB-Hib and pneumococcal vaccination as part of the Dutch National Immunization Program
2. Healthy infants
3. Full term born

Participant type(s)
Healthy volunteer

Age group
Neonate

Sex
Both

Target number of participants
56

Key exclusion criteria
1. Infants who had been previously been subjected to invasive medical procedures other than the routine medical care neonatal screening heel-lancing

Date of first enrolment
01/10/2014

Date of final enrolment
15/12/2014

Locations

Countries of recruitment
Netherlands

Study participating centre
University Medical Centre Groningen
Hanzeplein 120
Groningen
Netherlands
9919je

Sponsor information

Organisation
University Medical Centre Groningen

Sponsor details
Hanzeplein 1
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9700RB

Sponsor type
University/education

ROR
https://ror.org/03cv38k47

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
The Public Child Healthcare organization of Groningen (GGD)

Results and Publications

Publication and dissemination plan
Intention to publish the results regarding the pain scores, cry duration and possible adverse effects in a peer reviewed paper.

Intention to publish date
31/12/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request