

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

Submission date 12/11/2015	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 06/12/2015	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 30/05/2017	Condition category Signs and Symptoms	☐ 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

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.

Primary study design

Interventional

Study design

Single-centre randomised controlled trial

Study type(s)

Other

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(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Neonate

Sex

All

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

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request