

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

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<b>Registration date</b> 06/12/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 30/05/2017	<b>Condition category</b> Signs and Symptoms	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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**  
Mrs Netty Bos-Veneman

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## Additional identifiers

**Protocol serial number**  
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

## **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