

Information and consent form

Dear Sir/Madam,

Your child is currently residing in a day-care centre. For this reason, you are invited to let your child participate in an epidemiological study on the carriage of pneumococci and other bacteria in the nasopharynx (part of the throat connecting to the nose). Please do take the time to read through this document carefully.

Purpose of the study

The main purpose of this study is to monitor the carriage of pneumococci in the nasopharynx in a large group of children. The study will also examine the type (serotype) and resistance to antibiotics of the pneumococci carried. Pneumococci are bacteria which can cause infections in young children such as otitis (inflammation of the ear) or pneumonia, but they mostly remain, even if only temporarily, in the nasopharynx without causing any problem. The general use of pneumococcal vaccines on young children, as is the case in Belgium, leads to a decrease in the carriage of the serotypes which feature in the vaccines. This study, which was launched in 2016, is vital in terms of gaining an insight into the evolution of pneumococci and other bacteria which occur in the nasopharynx. The study will also investigate characteristics associated with carriage of pneumococci and other bacteria, including genetic factors of the infant. Already from the very first months of life, pneumococci may be present in infants, just like in all of us, in the nasopharynx without this being linked to any illness. In some circumstances, the carriage of pneumococci occurs more, such as in the case of acute otitis media.

Course of study

2,500 children residing in day-care centres will participate in this study over 3 years.

Who can participate:

- children aged between 6 and 30 months at the moment of sampling
- those who have not taken oral antibiotics in the previous 7 days
- those not suffering from any serious and long lasting illness

How the study is carried out

In the day-care centre of your child, a nurse will take a sample from your child's nose (one nostril) using a cotton bud. This is a painless procedure. Via a questionnaire, you will also be asked some questions regarding your child's health and vaccination status. If you agree, we can check your child's vaccination status via Vaccinnet or ONE. There will obviously be no costs incurred by you for your child participating in this study. The costs of taking and analysing samples are fully borne by the initiator of the project.

What happens with the nasal sample that is taken

After being taken, the sample is sent to the reference laboratory for pneumococci (Gasthuisberg University Hospital, Leuven) for analysis. The nasal sample from your child will be analysed for the presence of pneumococci and, if they

Study into the carriage of pneumococci in the nasopharynx among healthy infants aged 6-30 months residing in day-care centres in Belgium

are present, their type and resistance to antibiotics will also be examined. There will also be a search for other bacteria which may cause respiratory diseases or otitis.

The nasal sample taken will be stored at a very low temperature (-80 °C) for any additional examination in the future. If you agree, it can be analysed for the carriage of other germs which can cause respiratory diseases, and it can be used to investigate whether in young children genetic markers are associated with carrying the bacteriae investigated in this study.

Insurance and remuneration

This is a non-commercial study financed by study funds from the Centre for the Evaluation of Vaccinations at the University of Antwerp.

In accordance with the Belgian Act relating to Experimentation on Humans of 7 May 2004, the protocol for this study was assessed by the Ethics Committee of Antwerp University Hospital and the University of Antwerp. A legal liability insurance policy has been taken out by the University of Antwerp.

Right of refusal

Your child's participation in this study is completely voluntary. You are entitled at any time to terminate participation for any reason whatsoever. On the other hand, the CEV or nurse who took the sample, can also decide to stop participation if the guidelines are not followed, if your child is disadvantaged by the study or for administrative reasons. In any case, you retain the entitlement to normal medical care and you will not be disadvantaged in terms of medical care received or the possible participation of your child in future scientific studies.

Data protection

The personal data received as part of this study will be handled in confidence. Contact details required to make a one-off phone contact are removed after this contact has been made. Identification will subsequently occur on the basis of a study number. The encoded data is stored for a minimum of 20 years and will only be used to achieve the purpose of the study as presented to you. With this purpose in mind, your child's encoded medical data is transferred to the initiator of the study and to persons or organisations which come under its responsibility in Belgium or abroad. Access to this data may be granted, subject to the same terms on confidentiality, to the health authorities in Belgium to enable them to ensure that all the study data has been obtained and noted in the correct manner. Personal data about your child is not publicly available, nor in the case of reporting about the study.

In accordance with the legal provisions on gathering and processing data and on freedom, you are always entitled to view and amend your child's personal data. You are also entitled to stop the transfer of protected data as part of this study. In addition, you obviously have access directly or via the day-care centre to all of your child's medical details.

Possible discomfort and side effects

Taking a deep sample from your child's nose may be accompanied by a tickling or uncomfortable feeling, but it is completely painless.

Benefit for the participants

- Via the CEV, you can obtain information about the results of the study with regard to your child carrying pneumococci.

Study into the carriage of pneumococci in the nasopharynx among healthy infants aged 6-30 months residing in day-care centres in Belgium

- You are collaborating in a scientifically important study intended to gain a better insight into the carriage of pneumococci and other bacteria in the throat.
- There is no financial remuneration provided.

Contact details

If more information is required, in the case of a lack of clarity or any queries prior to or during the study, you can always obtain assistance from the responsible of you day-care centre or you can contact the Centre for the Evaluation of Vaccinations (CEV), which will carry out the study.

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Vaccin & Infectieziekten Instituut
Universiteit Antwerpen**



**VAXINFECTIO
Vaccin & Infectieziekten Instituut
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2610 Wilrijk

**Study into the carriage of pneumococci in the nasopharynx among healthy infants aged 6-30 months
residing in day-care centres in Belgium**

Participation number (to be filled in by investigator/nurse): 3DCC.....-

If you consent to participate in this study, we will ask you to read carefully and sign this information and consent form.

I,
.....(name and surname of legal representative),

the legal representative of
.....(your child's first name and surname)

hereby declares that I have been informed by
.....(name to be filled in by team member CEV)

about the nature of and participation in this study.

I have read the written information and have been able to ask sufficient questions about it, and I am satisfied with the replies and explanations which I have received. I have been given the time to reflect on the participation of my child in this study. I understand that I grant access to my child's data to authorised persons who are mentioned in this information form. I am completely at liberty to confirm or refuse the participation of our child. I agree that our child is participating in this study on the conditions described in this information form. I give my consent to the investigators to use encoded data for analysis and reporting. I understand that I am entitled to view the data and request amendments if necessary.

I give my consent to a specific genetic analysis of the nasal sample from my child for host conditions which may influence the detection of carrying pneumococci and other bacteria investigated in this study.

Yes

No

I give my consent for my child's nasal sample also to be used to investigate respiratory infections other than the respiratory conditions mentioned in this information form.

Yes

No

I give my consent to the verification of my child's vaccination dates via Vaccinnet or ONE.

Yes, postal code and address:.....

No

Date:.....

Legal representative's signature:.....

Signature nurse/investigator:.....

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residing in day-care centres in Belgium**

Participation number (to be filled in by investigator/nurse): 3DCC.....-.....

If you consent to participate in this study, we will ask you to read carefully and sign this information and consent form.

I,
.....(name and surname of parent),

the legal representative of
.....(your child's first name and surname)

hereby declares that I have been informed by
.....(name to be filled in by team member CEV)

about the nature of and participation in this study.

I have read the written information and have been able to ask sufficient questions about it, and I am satisfied with the replies and explanations which I have received. I have been given the time to reflect on the participation of my child in this study. I understand that I grant access to my child's data to authorised persons who are mentioned in this information form. I am completely at liberty to confirm or refuse the participation of our child. I agree that our child is participating in this study on the conditions described in this information form. I give my consent to the investigators to use encoded data for analysis and reporting. I understand that I am entitled to view the data and request amendments if necessary.

I give my consent to a specific genetic analysis of the nasal sample from my child for host conditions which may influence the detection of carrying pneumococci and other bacteria investigated in this study..

Yes

No

I give my consent for my child's nasal sample also to be used to investigate respiratory infections other than the respiratory conditions mentioned in this information form.

Yes

No

I give my consent to the verification of my child's vaccination dates on Vaccinnet or ONE.

Yes, postal code and address:.....

No

Date:.....

Legal representative's signature:.....

Signature nurse/investigator:.....

Questionnaire and case report form for healthy infants in day-care centres

Participation number (to be filled in by investigator/nurse): 3DCC - _____.

Date of birth infant: _____ / _____ / _____.

Sex infant: M

F

Method of child care: Day-care centre (\geq 2d/week)

Day-care centre (<2d/week)

Baby sitter (\geq 2d/week)

Baby sitter (<2d/week)

Information about participation

Information and informed consent signed

Not yet included during current school year

(not yet sample taken for this study between October 2017 and June 2018)

No severe and long lasting health problems

Information about participant and family

Infant already included (sample taken) in this study in past school years:

Yes, school year(s) _____.

No

Smoking habit parents:

Both do not smoke

One or both do not smoke anymore _____.

One or both smoke outside

One or both smoke inside

Premature (infant born < 37 weeks):

Yes

No

Is/was the infant breastfed (at least twice a day, may be combined with bottle feeding):

Never or < 6 months

\geq 6 months but not anymore

Infant currently receives breast feeding

continuation 

Carriage of pneumococci in the nasopharynx among healthy infants
aged 6-30 months residing in day-care centres in Belgium

Number of siblings within same household:

_____.

Previous illness with hospitalisation:

Yes

No

Previous history of acute middle ear infection (AOM):

Yes, number of AOM: _____.

No

Number of antibiotic treatments in the past 3 months:

_____.

If more than 0,

name last antibiotics:

_____.

date start last antibiotic treatment:

_____.

date last treatment was finished:

_____.

***Pneumococcus* vaccination:**

Yes

No

Please add copy of administered vaccinations or leave vaccination booklet at the day-care on the day of sampling!

date vaccination 1: _____ / _____ / _____.

Prevenar 13

Synflorix

date vaccination 2: _____ / _____ / _____.

Prevenar 13

Synflorix

date vaccination 3: _____ / _____ / _____.

Prevenar 13

Synflorix

date vaccination 4: _____ / _____ / _____.

Prevenar 13

Synflorix

Date: _____ / _____ / _____.

Signature legal representative: _____.

Do you have questions or would you like more information?

Please contact us:

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<https://www.uantwerpen.be/en/rg/cev/>