Title of the study: Impact of clinical guidance & point-of-care CRP in children: the ARON project

Sponsor of the study: KU Leuven represented by UZ Leuven

Research organisation: Academic Centre of General Practice, KU Leuven

Medical Ethics Committee: Ethics Committee Research UZ/KU Leuven (central committee) and Ethics Committee of UZA/UAntwerpen, UZ/UGent, ULiège, VUB, UCLouvain (local committees)

Local investigators: _____

I Information vital to your decision to take part

Introduction

Your child is being invited to take part in a clinical study to evaluate a diagnostic decision tree for the clinical management of your child's disease. The sponsor and clinical investigator hope that this may offer advantages in the treatment of patients with the same disease as your child. There is, however, no guarantee that your child will benefit from taking part in this study.

Before you agree to take part in this study, we invite you and your child to take note of its implications in terms of organisation, possible risks and benefits, to allow you to make a well-informed decision. This is known as giving "informed consent".

Please read these few pages of information carefully. For any queries you have, we refer you to the clinical investigator or his/her representative. There are 3 parts to this document: the information essential to your decision, your written consent, and supplementary information (appendices) detailing certain aspects of the basic information.

If your child takes part in this clinical study, you should be aware that:

- This clinical study is being conducted after having been reviewed by one or more ethics committees.
- Your child's participation is voluntary and must remain free from any coercion. It requires the signature of a document expressing your consent. Even after having signed this document, your child can stop taking part by informing the clinical investigator they wish to do so. The reason as to why you or your child want to cease participation in the study could be of interest of the researchers, but you have the right not to report this reason. The decision not to take part or to stop taking part in the study will have no impact on the quality of care or on the relationship with the clinical investigator.
- The data collected on this occasion are confidential and your child's anonymity is guaranteed during publication of the results.
- Insurance has been taken out in case your child should suffer any damage in connection with his/her participation in this clinical study.
- You will not incur any charges for the visits/consultations, examinations or treatments specific to this study.
- You may contact the clinical investigator or a member of his/her team at any time should you need any additional information.

Further information about the "Rights as a participant in a clinical study" can be found on page 5.

Objectives and description of the study protocol

We are inviting your child to take part in a clinical study. The aim of the study is to test whether a decision tree can accurately advise physicians when antibiotics are not needed. The study wishes to include 6111 acutely ill Belgian children aged 6 months to 12 years.

The decision tree combines several elements including a finger-prick test for an inflammatory marker (called C-reactive protein or CRP). Your physician will perform this test during the consultation (see the table below for more details). In a previous study the decision tree used to determine when antibiotics are not needed was validated. With this large study we look to confirm that the decision tree can safely advise when antibiotics ought not to be prescribed, compared to standard care (the physician deciding in the usual way, without the extra advice of the decision tree.

This is a randomized study comparing the decision tree with current standard care. This means that the participating general or paediatric practices are allocated to 2 groups by chance: (1) the test group – the decision tree will advise the physician when antibiotics are not needed, (2) the standard of care group, whether your child needs antibiotics, will be decided by the physician as per usual care.

Afterwards, you will be asked to fill in a digital diary in the form of a smartphone application. Your child's doctor will collect additional information up to 30 days after the consultation documenting the disease course over time.

Course of the study

Your child's participation in the study will last 30 days at most.

A number of additional procedures are required in the context of the study (more information in annex page 5). Your child's medical examiner can tell you which group (s)he has been allocated to. If you decide that your child is allowed to participate in the study and (s)he meets all the conditions for participation, (s)he will undergo the following tests and examinations, depending on the assigned group:

Test	Explanation	Timepoint
Decision tree (only in the intervention group)	Using a decision tree based on signs and symptoms, as a tool for evidence-based medical decision making	During the consultation
CRP point-of-care test (only in the intervention group)	Your child might receive a fingerprick for the CRP point-of-care test. The CRP level is determined with 1 drop of blood, the result is available after 4 minutes. The CRP level gives an indication of the presence of inflammation in the body.	During the consultation
Safety net advice (only in the intervention group)	During your child's consultation you will receive a booklet with information about the sickness of your child, alarm signs and what to do when these alarm signs occur.	During the consultation
Diary	You will be asked daily to register some basic information on your child's health status in an smartphone app, this will take about five minutes. Questions include whether (s)he has taken any medication and whether a doctor has been consulted.	Every day after the consultation until your child is feeling better or for a maximum of 30 days
Data collection	The clinical investigator collects data on the identity of your child and medical information, e.g. clinical signs and symptoms, medication, referrals and additional investigations (data flows are separated).	During the consultation
Data collection	The clinical investigator collects relevant medical data, e.g. medication, hospitalisation, re-consultation and additional investigations.	The clinical investigator fills in the follow-up form at least 30 after the consultation

Risks and discomforts

For children in the intervention group: by participating in the study your child might get a finger prick. This also happened in our previous study, and our experience shows that it causes moderate to little pain in children for a very short time. There are no other risks associated with the finger prick.

For parents of all participating children: until your child is feeling better, we also ask 5 minutes of your time each day to fill in a diary via a smartphone app.

Benefits

The information obtained from this study may contribute to a better knowledge of the use of this decision tree for the clinical management of infections in future patients.

Participants will not be financially compensated.

Withdrawal from the study

Your child's participation is voluntary, and you are entitled to withdraw your child from the study for any reason, without having to justify your decision. Nevertheless, it may be useful for the clinical investigator and for the

sponsor of the study to know if you or your child are withdrawing because the constraints of the clinical management are too large.

It is also possible that the clinical investigator withdraws your child from the study because he/she thinks it is better for your child's health or because he/she notices that you or your child are not following the instructions given to participants.

Finally, the competent national or international authorities, the ethics committee that initially approved the study or the sponsor may break off the study because the information gathered shows that the investigational clinical management is not effective (does not deliver a sufficient level of improvement in the health of the participants), the investigational clinical management causes more side effects or more serious side effects than anticipated, or for any other reason.

Treatment after stopping the study

In all these situations of withdrawing from the study, but also when the scheduled participation period has ended, your child's clinical investigator will assess your child's state of health and prescribe the best clinical management available.

Samples of biological material collected during the study

The sponsor of the study undertakes that the samples will only be used within the context defined in the section "Progress of clinical research" and its appendices.

If your child takes part in this clinical study, we ask you:

- To cooperate fully in the smooth progress of this study.
- Not to conceal any information relating to your child's state of health, the medication your child is taking or the symptoms your child is experiencing.

Contact

If you need further information, but also if you have problems or concerns, you can contact the clinical investigator (your GP or paediatrician) or a member of his/her research team (contact details at the top of this form).

In case of a non-urgent medical problem, please contact your GP or the after-hours service. In case of an urgent medical problem, you can do the same or contact A&E or call the number 112.

If you have any questions relating to your and your child's rights as a participant in a clinical study, please contact the ombudsman of your academic hospital (016 34 48 18). When necessary the ombudsman will refer you to the Ethics Committee.

II Informed consent

Participant

I declare that I have been informed of the nature of the study, its purpose, its duration, any risks and benefits and what is expected of me and my child. I have taken note of the information document and the appendices to this document.

I have had sufficient time to think about it and discuss it with a person of my choice, such as my physician or a member of my family.

I have had the opportunity to ask any questions that came to mind and have obtained a satisfactory response to my questions.

I understand that participation of my child in this study is voluntary and that I am free to end my child's participation in this study without this affecting my child's relationship with the therapeutic team in charge of my child's health.

I understand that data about my child will be collected throughout my child's participation in this study and that the clinical investigator and sponsor of the study will guarantee the confidentiality of these data in accordance with applicable European and Belgian legislation. I understand that this study serves the general interest and that the processing of my child's personal data is necessary for the performance of this study.

I agree to my child's GP or other specialists in charge of my child's health being informed of his/her participation in this clinical study.

I have received a copy of the information to the participant and the informed consent form.

Surname and first name of the child.

_____

Surname, first name, date and signature of the parent(s)

_____

Clinical investigator

I, the undersigned, _____, clinical investigator, confirm that I have verbally provided the necessary information about the study and have given the participant a copy of the information document.

I confirm that no pressure was applied to persuade the participant to agree to take part in the study and that I am willing to answer any additional questions if required.

I confirm that I operate in accordance with the ethical principles set out in the latest version of the "Helsinki Declaration", the "Good Clinical Practices" and the Belgian Law of 7 May 2004 related to experiments on humans.

_____

Surname, first name, date and signature of the clinical investigator

III Supplementary information

1: Supplementary information on the risks associated with participation in the study

Risks associated with the procedures of the clinical study

The **blood sample** (around 1 drop of blood) necessary for analysis of the CRP level may (rarely) cause pain, bleeding, bruising or infection localised around the injection site. Similarly, some patients may feel dizzy or even faint during the procedure. The staff who take the blood will do all they can to keep these discomforts to a minimum.

2: Supplementary information on the protection and the rights of the participant in a clinical study

Ethics Committee

This study has been reviewed by an independent Ethics Committee, namely the Ethics Committee of UZ/KU Leuven, which has issued a favourable opinion after consulting with the Ethics Committees of each centre where this trial will be conducted. It is the task of the Ethics Committees to protect people who take part in a clinical trial. They make sure that your and your child's rights as a patient and as a participant in a clinical study are respected, that based on current knowledge, the balance between risks and benefits remains favourable to the participants, that the study is scientifically relevant and ethical.
The Ethics Committees issue an advice in accordance with the Belgian law of 7 May 2004.

You should not under any circumstances take the favourable opinion of the Ethics Committee as an incentive to take part in this study.

Voluntary participation

Before signing, do not hesitate to ask any questions you feel are appropriate. Take the time to discuss matters with a trusted person if you so wish.

Your and your child's participation in the study is voluntary and must remain free of any coercion: this means that you have the right not to take part in the study or to withdraw without giving a reason, even if you previously agreed to take part. Your decision will not affect your relationship with the clinical investigator or the quality of your child's future therapeutic care.

If you agree to your child taking part, you will sign the informed consent form. The clinical investigator will also sign this form to confirm that he/she has provided you and your child with the necessary information about the study. You will receive a copy of the form.

It is advisable for your child's safety to inform the clinical investigator if you or your child have decided to stop taking part in the study.

Costs associated with your child's participation

The client has applied for funding for this study and obtained it from the Belgian Health Care Knowledge Centre (KCE). This allows us to reimburse the clinical investigators and their teams for the time they invested in the study and for all additional investigations that were performed in light of this study.

If you and your child decide to take part in this study, this does not entail any additional costs for you, your child or your insurer. You may only be charged for the costs corresponding to the standard medical care in the clinical situation of your child.

Guarantee of confidentiality

Your child's participation in the study means that you agree to the clinical investigator collecting data about your child and to the study sponsor using these data for research purposes and in connection with scientific and medical publications.

The processing of your child's personal data is necessary to achieve the scientific research purposes as set out herein. The conduct of scientific research is one of the core missions of KU Leuven as defined by law. As a university hospital, part of KU Leuven, KU Leuven is indeed required to support research and education in the public interest. KU Leuven clarifies that in light of this study she will process personal data of your child. This processing is legally permitted, given it is required for the scientific research KU Leuven conducts for the public interest. KU Leuven is also subject to specific legal requirements which require the processing of your child's

personal in the context of safety reporting (such as for example the notification of adverse events to the regulatory authorities). KU Leuven shall act as data controller for your child's data.

Your child's data will be processed in accordance with the:

- European General Data Protection Regulation (GDPR) of 27 April 2016 (into force since 25 May 2018)
- Belgian Privacy Act of 30 July 30 2018 (published 5 September 2018) on the protection of individuals with regard to the processing of personal data
- Belgian Law of 22 August 2002 on Patients' Rights.

You are entitled to ask the clinical investigator what data are being collected about your child and what is their use in connection with the study. This data concerns your child's current clinical situation but also some of your child's background, the results of examinations carried out within the context of care of your child's health in accordance with the current standards and obviously the results of examinations required by the protocol. You and your child have the right to inspect these data and correct them if they are incorrect[1].

The clinical investigator has a duty of confidentiality vis-à-vis the data collected.

This means that he/she undertakes not only never to reveal your child's name in the context of a publication or conference but also that he/she will encode (your child's identity will be replaced by an ID code in the study) your child's data before sending them to the manager of the database of collected data (Academic Centre of General Practice, KU Leuven).

The clinical investigator and his/her team will therefore be the only ones to be able to establish a link between the data transmitted throughout the study and your child's medical records[2].

The personal data transmitted will not contain any combination of elements that might allow your child to be identified[3].

For the study data manager designated by the sponsor, the data transmitted will not allow your child to be identified. The latter is responsible for collecting the data gathered by all clinical investigators taking part in the study, processing them and protecting them in accordance with the requirements of the Belgian law on the protection of privacy.

To verify the quality of the study, it is possible that your child's medical records will be examined by persons subject to professional secrecy and designated by the ethics committee, the sponsor of the study or an independent audit body. In any event, this examination of your child's medical records may only take place under the responsibility of the clinical investigator and under the supervision of one of the collaborators designated by him/her.

The (encoded) study data will be able to be sent to Belgian or other regulatory authorities, to the relevant ethics committees, to other doctors and/or to organisations working in collaboration with the sponsor.

They will also be able to be sent to other sites of the sponsor in Belgium and in other countries where the standards in terms of the protection of personal data may be different or less stringent. As explained above, the transmitted data are encoded[4].

Your and your child's consent to take part in this study therefore also the use of your child's encoded medical data for the purposes described in this information form and to their transmission to the aforementioned people and authorities.

The sponsor will use the data collected within the context of the study in which you and your child are taking part but would also like to be able to use them in connection with other research concerning the same disease as your child's. Any use of your child's data outside the context described in this document is only possible with the approval of the ethics committee.

[1] These rights are guaranteed by the European Data Protection Regulation (GDPR) and by the Law of 22 August 2002 on patient rights.

[2] For clinical trials, the law requires this link with your records to be retained for 20 years. In the case of a advanced therapy medicinal product using human biological material, this period will be a minimum of 30 years and a maximum of 50 years in accordance with the Belgian Law of 19 December 2008 on the use of human biological material and the applicable royal decrees.

[3] The database containing the results of the study will therefore not contain any combination of elements such as your initials, your gender and your full date of birth (dd/mm/yyyy).

[4] The sponsor then undertakes to respect the constraints of the European General Data Protection Regulation (GDPR) and the Belgian legislation on the protection of natural persons with regard to the processing of personal data.

By agreeing to participate in this study, your child's data from this study may be used by the sponsor and the funder (KCE) or similar public health research institutes in Europe for further analysis, e.g. to determine which of the clinical management approaches studied is preferable in terms of efficacy and cost-effectiveness.

The KCE is an independent research center that provides scientific advice on healthcare topics. The purpose and tasks of the KCE are set out in Articles 262 to 268 of the Program Law (I) of December 24, 2002. As part of these tasks, the KCE must have access to certain personal data related to the health of the Belgian citizens and has the task of performing analyzes based on coded data (pseudonymised data) in the public interest. If KCE takes the initiative for this, the following procedure applies. For these future projects, KCE or the similar public health research institutes in Europe will, as data controller, request permission from the Social Security and Health Chamber of the Information Security Committee (IVC) in accordance with the relevant legislation. The decisions of the IRPC are public and can be consulted on the website of the ICV (https://www.ehealth.fgov.be/ehealthplatform/nl/sectoraal-comite/documenten). The KCE reports are also publicly available (https://kce.fgov.be/nl/publicaties/alle-rapporten). It is not possible for the KCE to inform you personally because the KCE does not have your contact details. You agree that for these further analyses your child's Belgian national number is collected and used by a trusted third party to link your child's study data to data from other sources (healthcare billing data on hospitalisation, consultations, and reimbursed medications and minimal clinical data sets collected during any hospital stay).

If you withdraw your and your child's consent to take part in the study, to guarantee the validity of the research, the data encoded up to the point at which your withdrawal will be retained. No new data may be sent to the sponsor.

If you have any questions about how we use your data or if you want to exercise your right to access, correct, stop further processing, you can always contact your GP-researcher at the following contact address: see details on page 4. If you have any special points for attention afterwards or if you wish to file a complaint, you can contact the privacy team of KU Leuven at privacy@kuleuven.be.

Finally, if you have a complaint concerning the processing of your child's data, you can contact the Belgian supervisory authority who ensures that privacy is respected when personal data are processed.

The Belgian supervisory authority is called:
Data Protection Authority (DPA)
Drukpersstraat 35,
1000 Brussels
Tel. +32 2 274 48 00
e-mail: contact@apd-gba.be
Website: https://www.dataprotectionauthority.be

Insurance

Any participation in a clinical study involves a risk, however small it is. Even if there is no fault, the sponsor accepts responsibility for damage caused to the participant (or in the event of death, his/her dependants) and directly or indirectly linked to his/her participation in the study. You or your child therefore do not have to demonstrate fault for this. The sponsor has taken out insurance for this responsibility[5].

If the clinical investigator believes that a link with the study is possible (the insurance does not cover the natural progression of your child's disease or the known side effects of your child's normal treatment), he/she will inform the study sponsor, which will initiate the declaration procedure to the insurance company. The latter will appoint an expert - if it considers it necessary - to assess whether there is a link between your child's new health problems and the study.

In the event of disagreement either with the clinical investigator or with the expert appointed by the insurance company and also whenever you feel it is appropriate, your child or - in case of death – your dependants may bring proceedings against the insurer directly in Belgium (Amlin Insurance SE, contractnumber 299.053.700, Vanbreda Risk & Benefits NV, Plantin en Moretuslei 297, 2140 Antwerpen).

The law provides that the insurer may be summoned to appear either before the judge of the location where the event giving rise to the damage occurred, or before the judge of your domicile, or before the judge of the insurer's registered offices.

[5] In accordance with Article 29 of the Belgian Law related to experiments on humans (7 May 2004)

Study title: 1) Cost-effectiveness analysis of clinical management and point-of-care CRP in children

2) Impact of clinical management & point-of-care CRP in children: Qualitative study of parents' experiences through interviews

Sponsor of the study: KU Leuven represented by UZ Leuven

Research organisation: Academic Centre of General Practice, KU Leuven

Medical Ethics Committee: Ethics Committee Research UZ/KU Leuven (central committee) and Ethics Committee of UZA/UAntwerpen, UZ/UGent, ULiège, VUB, UCLouvain (local committees)

Dear Sir, dear Madam,

Your child is participating in the ARON study. This is a clinical study that, with the help of a decision tree, accurately advises doctors when antibiotics are not necessary. This letter informs you about 1) a cost-effectiveness analysis and 2) a qualitative study set up in the context of the ARON project.

PART I: Cost-effectiveness analysis

1.1 Introduction

It is possible that the cost-effectiveness of this decision tree will be assessed. Such an analysis only has a clear added value if the decision tree proves to be clinically effective compared to usual care. This means that a health economic analysis will only be performed if the decision tree provides a benefit in terms of health and quality of life. A health economic evaluation involves assessing the relationship between the price and the benefit of the intervention in terms of health and quality of life. A cost-effectiveness analysis can provide very valuable information before an intervention is routinely introduced into ambulatory care.

You have already confirmed your child's participation by signing an informed consent form during your consultation with your sick child with your doctor-investigator (General practitioner or Paediatrician). This form already contained a brief mention of the possibility that a cost-effectiveness study would follow.

We would like to use this information letter to give you some more information about the possible cost-effectiveness study that will follow the clinical trial. We ask you to read the following pages of information carefully.

1.2 Objective and description of the health economic analysis

The main objective of the health economic analysis is to determine whether the treatment, in particular the application of the decision tree, is cost-effective.

In order to carry out this health economic analysis in a methodologically correct way, data from the original clinical trial are needed, such as diagnosis, but also data such as age, gender and other variables. These variables are required per randomization group: the intervention group (in which the decision tree is applied) and the control group (usual care).

These personal data should be linked to expenditure from the payer's perspective, i.e. all costs for compulsory health insurance and patient until three months after consultation with the doctor in the ARON study. This linking of study data with data from external sources is done by a trusted third party (eHealth) on the basis of your child's national registration number. The linked data is then made available to the researchers.

The data relating to health-related costs are available within the databases of the InterMutualist Agency (IMA-AIM). The costs up to and including three months after the first consultation are necessary in order to properly assess the course of illness (use of medication, possible hospitalization and reconsultation) after your child's illness. Since a cost-effectiveness analysis compares the costs for the new intervention with the costs for standard care, the cost data are also needed for both groups.

Building a cost-effectiveness model requires the data on an individual level, but without the need for direct identification (pseudonymized data, i.e. your child cannot be identified).

In accordance with Article 14 paragraph 1 d) or 14 (2) (f) of the European General Data Protection Regulation (GDPR), please find below a justification for each category of pseudonymized variables that will be used in the health economic analysis.

Category of variables	Motivation
Information about reimbursed health care: Provider, number, number of days after the first consultation, cost... (Source: Health care database of the InterMutualist Agency)	These variables allow for the calculation of the total costs of provided care and/or hospital medication from the perspective of the care payer in the context of assessing the cost-effectiveness of the ARON intervention (decision tree) compared to standard care.
Information on each reimbursed medicine: Provider, number, number of days after first consultation, cost... (Source: Farmanet database of the InterMutualist Agency)	These variables allow for the calculation of costs of dispensed drugs from the perspective of the payer of the care in the context of assessing the cost-effectiveness of the ARON intervention (decision tree) compared to standard care.
Information on each hospitalization: Hospital, department, number of days after the first consultation, duration... (Source: Hospitalisation database of the InterMutualist Agency)	These variables allow us to calculate the cost of each hospitalization from the perspective of the payer of the care in order to assess the cost-effectiveness of the ARON intervention (decision tree) compared to standard care.
Demographic data: Age, sex... (Source: Registration by doctor during the first consultation as part of the ARON study)	Necessary in health economic analysis for subgroup analysis (analysis of a subset of all participants) to separately estimate costs for patient groups by gender, age, etc. Furthermore, these variables are required in the health economic analysis to make patient mix adjustments in the analysis. These adjustments use a technique whereby group influences are neutralized independent of the study arm in order to make a more correct comparison between study groups.
Medical data registered by the doctor in the permanent file of the clinical trial[1]: Diagnosis, anamnesis, treatment... (Source: Registration by doctor during the first consultation and 30 day follow-up period as part of the ARON study)	These variables allow to calculate the total cost of provided care and/or medication from the perspective of the payer of the care in the context of assessing the cost-effectiveness of the ARON intervention (decision tree) compared to standard care. Furthermore, they are required in health economic analysis for subgroup analysis to separately estimate costs for patient groups per diagnosis, history, etc. Furthermore, these variables are required in the health economic analysis to make patient mix adjustments in the analysis. These adjustments use a technique in which group influences are neutralized independent of the study arm in order to make a more correct comparison between study groups.

1.3 Confidentiality

KU Leuven is the data controller of your child's data. This processing is permitted by law, as it is necessary for the general interest in the field of public health.

Your child's data will be processed in accordance with the:
- European General Data Protection Regulation (GDPR) of 27 April 2016 (in force since 25 May 2018);
- Belgian Privacy Act of 30 July 2018 (published on 5 September 2018) on the protection of natural persons with regard to the processing of personal data;
- Belgian Patients' Rights Act of 22 August 2002.

[1] *The trial master file shall consist of essential documents enabling an assessment both of the conduct of a clinical trial and of the quality of the data generated. These documents must show whether the investigator and the sponsor have complied with the principles and guidelines of good clinical practice and with the applicable requirements, particularly those in Annex I to the Royal Decree of 3 July 1969 on the registration of medicines.*

The data obtained by linking will be kept for 5 years after publication of the KCE report. The personal data recorded in the permanent medical file of the clinical trial (cf. "data in the medical file" in ICF - version 2) will be kept for 20 years after the first consultation with the doctor in the framework of the ARON study. The data must be kept in a form that does not allow the data subjects to be identified for longer than is necessary for the purposes for which the personal data are processed.

1.4 Risks and inconveniences

There are no risks or discomforts associated with the ARON intervention for those involved**.**

1.5 Costs related to your participation

There are no costs associated with the health economic analysis of the ARON intervention for the persons concerned.

1.6 Benefits

There is no fee for you or your child to participate in the health economic analysis of the ARON intervention.

1.7 Ethical committees

The possibility to carry out a health economic analysis of the decision tree when it proves to be clinically effective compared to standard care has been evaluated by an independent ethical committee (Research Ethics Committee UZ/KU Leuven) which has given a favourable advice. The ethical committees check whether your rights as a patient and as a participant in a study are respected, whether - based on current knowledge - the balance between risks and benefits is favourable for the participants, and whether the study is scientifically relevant and ethically sound.

PART II: Qualitative study (interviews)

Within the framework of the ARON study, the following topics will be explored through interviews with parents: Parents' expectations of antibiotics for their sick child, parents' experience with the ARON study consultation, if applicable: parents' experience with the diagnostic algorithm (including point-of-care CRP test). Participation in this qualitative component is not mandatory and not every parent will receive an invitation. If you do qualify, you will be informed by a researcher.

Contact

If you have any questions about how we use your data or wish to exercise your right to access, correct and, if necessary, stop further processing, or in the event of problems or concerns, you can always contact the data protection officer (Toon Boon) at dpo@kuleuven.be or +32 16 32 40 74.
Should you have any further concerns or complaints, please contact the KU Leuven privacy team at privacy@kuleuven.be.

Finally, if you or your child has a complaint about the processing of your child's data, you can contact the Belgian supervisory authority that supervises compliance with the basic principles of personal data protection:

The Belgian supervisory authority is called:
Data Protection Authority
Rue du Mail 35,
1000 Brussels
Tel.: +32 2 274 48 00
E-mail contact(at)apd-gba.be
Website: www.gegevensbeschermingsautoriteit.be