APPENDIX 2

Parent information and consent form

PARENT INFORMATION

Individual antibiotic therapy for children with febrile urinary tract infection

Overview

- Children with febrile urinary tract infection are currently treated with 10 days of antibiotics, regardless of whether the child gets healthy within few days.
- Newer studies show that it is safe to shorten the antibiotic therapy for children with other kind of infections, thus avoiding unnecessary antibiotics.
- We want to investigate whether shorter antibiotic therapy to a febrile urinary tract infection, where the treatment duration is determined by how quickly the child recovers, is as effective as standard care.

Dear parents,
We would like to ask whether you would allow your child to enter a research project investigating whether we can shorten the antibiotic therapy for children with febrile urinary tract infection, who quickly gets healthy after treatment initiation. We plan to include about 400 children throughout East Denmark. Before you decide, we would like you to read this written information. It is of course voluntary to participate in the project, and you can always without any reason withdraw your consent.

Purpose
Currently, we treat all children with febrile urinary tract infections with 10 days of antibiotic therapy. No scientific studies exist that show that it is necessary to treat for 10 days. However, several studies have shown that the majority of children with febrile urinary tract infections are without any symptoms or fever 2-3 days after treatment initiation. Similar studies in children with e.g., pneumonia have shown that 3-5 days of antibiotic therapy is just as effective as 7-10 days. Currently, no study has assessed whether the duration of antibiotic therapy for children with febrile urinary tract infections can be shortened and if this can be done with an individualized approach.

Plan for project
We will contact you by phone about 3 days after your initial visit to the hospital. You will here be able to ask questions about the project. If you accept that your child can participate in the project, he/she will randomly be selected for one of the following two treatment strategies:

- New treatment strategy: the duration of antibiotic therapy will be determined by how quickly the child gets healthy.
- Standard treatment: antibiotic therapy will be given for 10 days.
All other aspects of the treatment will be the same in both groups.

If you do not want your child to participate in the project, your child will receive standard antibiotic therapy for 10 days.

**Side effects, risks, complications, and disadvantages**
We would like your child to participate in the project, as we consider that he/she is among the children with febrile urinary tract infections who without any risk can get healthy with a shorter duration of antibiotics. There is a small risk that the new treatment strategy does not have sufficient effect leading to your child getting a relapse. You will, therefore, be thoroughly informed of which signs of infection to look for. If you suspect that your child has got a relapse, you can directly contact the pediatric emergency department around the clock.

There might be some risks with the project which we do not know of yet. However, we do not expect that the new treatment strategy will lead to a higher risk of side effects or complications, neither in the short nor long term.

**Patient records and handling of personal information**
The research group will collect relevant health information from your child’s patient record. The health information collected will include information on the current infection episode, including the child’s condition, blood tests, bacterial examinations, and possibly imaging examinations. We will use this information to continuously monitor the project and at the end compare the two treatment strategies. The collected data will be assigned a code (patient number) resulting in that the data cannot be traced back to your child’s CPR number. The data will be kept for 10 years. The anonymized data will be kept in a database made for the project. The Data Protection Act and the Data Protection Regulation will be complied with.

**Electronic questionnaire**
You will in your e-Boks receive an electronic questionnaire every week in the first month after inclusion. The questions will include whether your child has experienced any specific side effects the previous week, as well as the number of days your child has been away from school or daycare due to illness. In addition, we will in the last questionnaire ask what you thought about participating in the project and about your child’s treatment.

**The benefits of the project**
The expected benefit of the project is that children with febrile urinary tract infection who recovers quickly after treatment initiation can receive shorter treatment in the future. This will lead to less exposure to antibiotics and fewer side effects. Moreover, the risk of antibiotic resistance will fall. However, we cannot promise that your specific child will get all these beneficial effects.

**Exclusion from the project**
The project can be terminated if unexpected significant complications are observed.
**Financial compensation**

No financial compensation will be given for participation in the project.

**Financial support**

The project has received financial support from the Danish Innovation Foundation (2 million Danish kroner) and the Capital Region (0.5 million Danish kroner). The financial support will cover salaries for study doctors, statisticians, urine sample analysis, and dissemination. None of the investigators are financially attached to private enterprises, foundations, etc. that have interests in the research project.

The project has been approved by the Ethics committee from the Capital Region with protocol number H-21057310.

On the next page, you will find information on your rights as a research participant. We hope that you with this information can decide on your child’s possible participation. If you want to know more about the project, you are more than welcome to contact us.

With kind regards,

**Project initiators, project doctors, and contact persons:**

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The rights of research participants in health science research projects

Information from the Ethics Committee

As a participant in a biomedical research project, you should know that:

- your child’s participation in the research project is completely voluntary and can only be done after you have received oral and written information about the research project and signed the declaration of consent.

- you at any time orally, in writing or by another clear statement can withdraw your consent. Withdrawing your consent will not affect your right to current or future treatment or any other rights you may have.

- you have the right to bring a family member, friend, or acquaintance to the information interview.

- you have the right to a period of reflection before you sign the declaration of consent.

- information about your child’s health conditions, other purely private matters, and other confidential information about your child that emerges in connection with the research project is subject to a duty of confidentiality.

- the storage of information about your child, including information from your child’s blood samples and tissue, will take place in accordance with the rules in the Personal Data Processing Act and the Health Act.

- it is possible to gain assess to document protocols in accordance with the provisions of the Public Assess Act. This means that you can assess all papers regarding your child’s participation in the experiment, expect for the parts that contain trade secrets or confidential information about others.

- it is possible to complain and receive compensation in accordance with the rules in the Act on Access to Complaints and Compensation within the Health Service. If an injury should occur during the trial, you can contact the Danish Patient Compensation Association, see more at https://pebl.dk/en.
Declaration of consent for participation in a biomedical research project

Title of the research project:
Individualized versus standard duration of antibiotic therapy in children with acute uncomplicated febrile urinary tract infection

Statement from the holder of parental responsibility:
I/we have received oral and written information, and I/we know enough of the purpose, methods, advantages, and disadvantages to give my/our consent. I/we know that it is voluntary to participate and that I/we always can withdraw my/our consent without my/our daughter/son losing any of her/his current or future rights for treatment.

SIGNATURES

I/we give our consent to that ______________________________________________________ Write child’s name (block letters) and CPR-number

participates in the research project and that her/his biological material is taken for storage in a research biobank. I/we have received a copy of this consent sheet including a copy of the written information material about the project for own use.

Name/names of the holder(s) of parental responsibility:
____________________________________        __________________________________

Write parents name (block letters)                                     Write parents name (block letters)

Date_______________________Signatur__________________________________________

Date_______________________Signatur__________________________________________

Do you wish to get informed about the results of the research project including any consequences for your child?
Yes__________ (put x)   No__________ (put x)

Statement from the person providing the information:
I declare that the parents/child have received oral and written information about the research project. In my opinion, sufficient information has been provided for the parents to decide on the child’s participation in the project.

SIGNATUR FROM INFORMING DOCTOR

Name________________________________________________________________________

Date_______________________ Signatur__________________________________________