

**PARENT/GUARDIAN INFORMATION SHEET**

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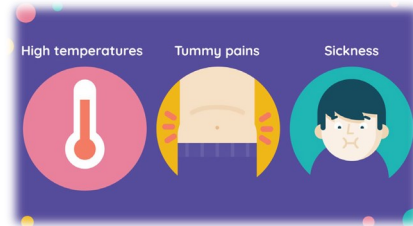
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**CURLY STUDY WEBSITE**

[www.curly.digital.com](http://www.curly.digital.com)

**We are inviting you and your child to take part in a research study called CURLY:**

- ◆ CURLY is a study which aims to improve the treatment of children who have urine (wee) infections with high temperatures. Urine infections are very common in children. They can cause high temperatures, tummy pains and vomiting. This can be distressing for children and parents. Urine infections are usually treated with an antibiotic medicine called cefalexin.



Symptoms

- ◆ In adults, just a few days of antibiotics is usually enough to stop the infection. However, doctors are not sure if this is the same for children. Shorter treatment with antibiotics has benefits over longer treatments. Shorter treatments have fewer side effects, like diarrhoea and sickness. Shorter treatments also mean that ‘bad bacteria’ don’t form. ‘Bad bacteria’ can be difficult to treat as some antibiotics can’t kill them. However, whilst short treatments have many advantages, doctors need to make sure that the treatment is long enough to cure the infection.



In adults we can usually stop the infection



Doctors are not sure if this is the same for children

- ◆ The study will compare different numbers of days of antibiotic treatment. If you decide to take part in the study your child will be given antibiotics for either 3, 5, 6, 8 or 10 days. The number of days will be decided using a fair process called randomisation. Whatever the number of days treatment given, we will monitor your child closely to make sure the infection goes away.



The number of days each child takes the medicine...



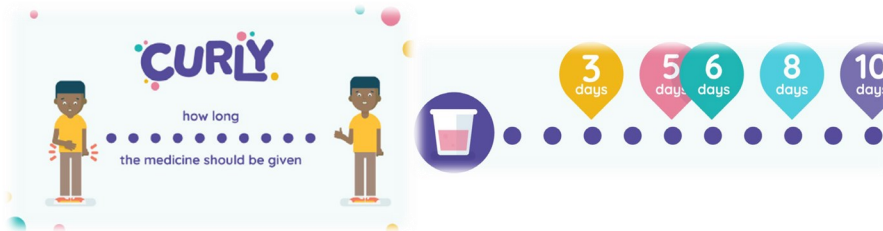
...will be decided by chance, using a process called randomisation

- ◆ At the end of the study, we hope we will know how many days of antibiotics is best for children with urine infections.
- ◆ It is important for you to understand why the study is being done, and what it will involve. Please ask your study doctor or nurse if anything is not clear or if you would like more information. Discuss it with family or friends if you wish.
- ◆ Your child does not have to take part in the study and you can stop taking part at any time. Your decision will not affect the level of care your child will receive.

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**1. Important things that you need to know:**

- ◆ Your child is being invited to take part in the CURLY study because they have a urine infection and can safely be treated with cefalexin liquid medicine at home after their visit to the Emergency Department.
- ◆ Doctors are not sure how many days of antibiotics is needed for the infection to go away.
- ◆ Your child will have either 3, 5, 6, 8 or 10 days of antibiotics. The number of days of treatment will be decided using a fair process called randomisation.



**The CURLY study will find out for how long the medicine should be given to children to make them better**

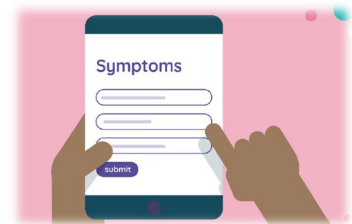
- ◆ You will go home with the right amount of antibiotics chosen for your child.
- ◆ We'd like you to keep in touch and tell us how your child is doing, using a mobile phone app.
- ◆ You will be asked to complete some questions about your child during their recovery. These questions will be asked at the start of the study and then two more times over the next four weeks.



**We will show families how to use an app**



**Keep track of the amount of medicine taken**

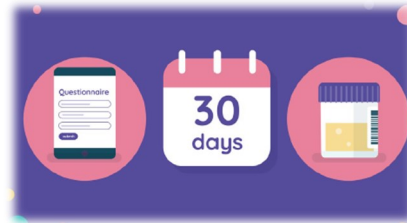


**Keep track of any symptoms that develop**

- ◆ In about **two weeks**, you will need to come to a follow-up hospital appointment (at a planned time) for an assessment of your child and to give a urine sample to check that the infection has gone. Your travel and parking expenses for this visit will be reimbursed.
- ◆ At the **end of the study (day 30)**, you will be asked to collect a final urine sample from your child at home and post it to us in a prepaid box. You will be given information on how to do this.



**2 weeks: The child will have an appointment to check the infection**



**30 days: Follow-up assessment from home and provide another wee sample that you post back to us**

- ◆ We will send you a £20 gift voucher at the end of the study, to thank you for your time and to reimburse you for the costs of any phone or internet data whilst using the app.

## 2. What treatment will my child receive if they take part?

The doctor looking after your child in the Emergency Department has decided that your child should be treated with an antibiotic called cefalexin. This is based on what you've told them about your child's illness and what they found when they examined your child, and the test results from your child's urine.

If you take part in the CURLY trial, your child will receive either 3, 5, 6, 8 or 10 days of antibiotic treatment. The group that your child is put into is decided using a study process called randomisation. This means there is an equal chance of being placed in each group. This is the best way to ensure that there is a fair comparison between groups.



## 3. What will happen if my child takes part

If you decide you would like your child to take part, a member of the study team will ask you to complete:

1. A consent form. Older children will also be asked to complete an assent form which means that the child also gives their permission to take part.
2. A contact information form so we can contact you about your child's recovery.
3. A questionnaire about your child's recent symptoms and brief information about their medical history and general wellbeing.

Before you go home a member of the research team will provide you with the CURLY app and show you how to use it. The app can be used on your phone, tablet or computer. We will ask you to use this app to track when you give your child antibiotics and any other medication. You will also need to record any symptoms during this time.

**On the last day of treatment** you will receive an alert via text or email to remind you that the antibiotic treatment is due to finish. **48-72 hours after the antibiotics finish** you will be asked to reply to a text or email to let the research team know how your child is getting on.

**On day 16** your child will have a hospital appointment with the research team, at a planned time, so that we can ask about any symptoms that they still have. We will also ask you some questions about your child's quality of life. If you are worried that your child has not fully recovered the doctor can examine your child. Another urine sample will also be collected to check that the urine infection has completely cleared. If the result is not normal, we will contact you and give you extra antibiotics to deal with this.

**On day 30** you will be asked to reply to a final text or email so that we can find out if your child is well. You will also be asked to collect a third urine sample from your child at home. You will be given instructions on how to collect the sample. You can simply post the sample back to the research team in a pre-paid box. This sample will be tested to check that the urine infection hasn't returned. Again, if the result is not normal, we will get in touch and give extra antibiotics to deal with this. If the result is normal, we will not contact you.

Before you go home	<ul style="list-style-type: none"> <li>◆ CURLY smartphone app provided and explained</li> <li>◆ Treatment twice a day with cefalexin antibiotic</li> </ul>
Antibiotic treatment for either the next 3, 5, 6, 8 or 10 days	<ul style="list-style-type: none"> <li>◆ Daily recording of your child's symptoms and medicine use on the app</li> <li>◆ Text/email alert on final day of treatment to remind you to finish</li> </ul>
48-72 hours after antibiotic treatment	<ul style="list-style-type: none"> <li>◆ Reply to a text/email to let the research team know how your child is getting on</li> </ul>
Day 16	<ul style="list-style-type: none"> <li>◆ Visit with the study nurse at the hospital</li> <li>◆ Collect urine sample from your child</li> </ul>
Day 30	<ul style="list-style-type: none"> <li>◆ Reply to a text/email to let the research team know how your child is getting on</li> <li>◆ Collect urine sample from your child at home and post this to the study team</li> </ul>

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#### 4. What tests will my child need?

##### Standard tests for all children with suspected urine infections.

The sample of urine that has already been collected from your child will be sent to the laboratory for standard hospital tests. If bacteria grow in the urine sample in the next two days, this will confirm that your child has a urine infection. The laboratory will also check that your child is getting the right treatment by testing a group of different antibiotics which should work to kill bacteria in the urine. If the tests show that cefalexin does not kill the bacteria, the hospital will get in touch to change your child's medicine.

##### Extra tests for children in the CURLY study

Two extra samples of urine will be collected from children in the CURLY study. A sample on day 16 will be tested to check that the infection has completely cleared. The sample on day 30 will be tested to check that the infection has not returned. We will contact you if any these tests are not normal.



Urine samples will be collected for laboratory tests at Day 16 at the ED appointment and at Day 30 from home and posted back to us

If any of these tests show that cefalexin does not kill the bacteria, we may do some further tests to help us to understand how this happens. The bacteria samples will be transferred to our research laboratory in the University of Birmingham for this.

#### 5. What are the possible benefits and drawbacks of taking part?

Cefalexin is a very safe medicine. We use it for most urine infections in children. Your child would be given cefalexin to treat their urine infection even if the study was not happening. You may want to think about the possible benefits and drawbacks of taking part in CURLY.

##### What are the possible benefits?

- ♦ Children who take shorter treatments of cefalexin may have fewer side effects (*see section 6 below*).
- ♦ Shorter treatments of antibiotics also stop 'bad bacteria' from forming. 'Bad bacteria' can be difficult to treat as some antibiotics can't kill them.
- ♦ We will monitor your child more closely than normal, using the information that you give on the app and with an extra hospital appointment. This means we can make sure your child is doing well, spot very early if further help is needed, and we can give them more medicine if needed.
- ♦ We will also collect extra urine tests to make sure the bacteria has completely gone and contact you if this is not the case.
- ♦ You will also have a contact number for the research nurse in case of any worries.
- ♦ You will help children in the future as we will know the best number of days of cefalexin to give.

##### What are the possible drawbacks?

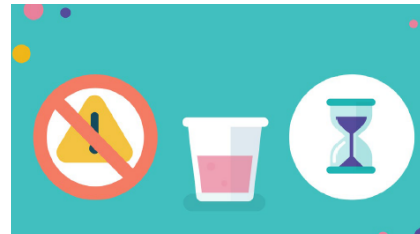
- ♦ Although it works in adults, a short treatment of antibiotics in children might not be as good at treating urine infections as longer treatments. However, the doctors will monitor your child closely and make sure that your child gets the right treatment to make sure that the infection is fully cleared.
- ♦ Children who take longer treatments of cefalexin may have more side effects. We will collect information from you to find out if this is the case.
- ♦ You will need to provide your time to complete the information on the app and to answer the text/email questions (about 5 minutes per day).
- ♦ You will be asked to come to the hospital for an extra visit with the study nurse on day 16. Your travel and parking expenses for this visit will be reimbursed. If there is a problem at this time, we will be able to start extra treatment straight away.

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**6. What are the possible side effects?**

Doctors have been using cefalexin to treat urine infections in children for many years. We know that it is a safe drug with very few side effects. About 1 in 10 children who take cefalexin will have mild diarrhoea or thrush. A full list of possible side effects will be provided inside the medicine packaging.

If you are concerned about side effects, please tell your study nurse or another healthcare provider (such as your hospital or your GP) as soon as possible.



**Cefalexin is very safe and is used to treat most urine infections. Side effects are minor and rare, it is better to take antibiotics for as little time as possible**

**7. What do I need to look out for?**

**What if I forget to give a dose of antibiotic?**

It is very important that you give your child the medicine as prescribed. The CURLY app will help you to track when you give the medicine to your child.

**Late dose:** If you forget to give a dose at the due time, you can still give it within 6 hours of the time at which you were originally planning to give it. The next dose should be given as normal.

**Missed dose:** If you forget to give a dose at the due time and it is not possible to give the dose within 6 hours of this due time, the dose should not be given. Please record this on the CURLY app. This is really important. If you are worried please contact your study nurse or another healthcare provider as soon as possible. The next dose should be given as normal.

**What if my child spits or vomits?**

If your child spits a dose out or vomits less than 30 minutes after a dose of antibiotic, you should give another full dose. Please let us know about this using the CURLY app. If it is more than 30 minutes, just give the next dose as normal. If spitting or vomiting happens repeatedly, you should get in touch with your study nurse or return to the Emergency Department.

**When should I seek medical advice?**

We expect that your child will start to feel better with the treatment they receive. Please contact your study nurse or another healthcare provider (such as your hospital or your GP) as soon as possible if you observe any of the following:

- ◆ Your child is very drowsy or sleepy, or is hard to wake
- ◆ Your child vomits a lot and is unable to drink much (you may notice that they are passing urine less than normal)
- ◆ Your child appears to be in a lot of pain, which does not improve after taking a pain medicine, such as paracetamol
- ◆ You are worried about your child at any stage during the illness

**8. Can my child take other medicines?**

Please tell the Emergency Department doctor about any other medications that your child is taking before your child starts treatment for the CURLY study.

Sometimes medicines such as paracetamol (e.g. Calpol) or ibuprofen (e.g. Nurofen) are given to children that have urine infections to help with pain and fever. These are not antibiotics and can be given alongside the cefalexin as you would normally use them.

Their main benefits are in reducing pain, reducing fever and helping them feel more comfortable. Please ask a pharmacist or read the packaging if you have any questions about the strength of medicine you are using or about the correct dose.

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### 9. OPTIONAL — Additional Research

Your child can take part in the main study above without participating in these extra studies.

#### **Gut bacteria sub-study**

Lots of bacteria live normally in our gut – these bacteria are mostly harmless and sometimes are helpful. These bacteria are affected by antibiotic treatment. This extra study will look at whether different number of days of cefalexin antibiotic medicine change the amount of bacteria in children's gut.

With your permission, we will collect a small sample of your child's stool (poo) at the hospital appointment on day 16. We can either collect this from inside a nappy, or a swab (like a cotton bud) can be used to wipe inside your child's bottom. The samples will be stored and tested at a laboratory at the University of Birmingham and won't have any identifying details from your child on them. They would just be identified by a code number.

#### **Future research on the urine bacteria**

Your child's urine samples will be tested at your local hospital. We would like to request your permission to perform future research on any bacteria that are found in these urine samples. The bacteria will be stored and analysed instead of throwing them away. You will be able to indicate on the consent form whether you are happy for us to do this. Any research using the bacteria from your child's urine samples will only be carried out if an independent research ethics committee has approved it. The bacteria samples will be stored at a laboratory at the University of Birmingham and will not have any identifying details from your child on them. They would just be identified by a code number.

### 10. How will my child's information be used and kept secure?

Your child's participation in the study and all information collected will be subject to the General Data Protection Regulation and the Data Protection Act (2018) and will be kept strictly confidential. We will need to use information from your child for this research project. This information will include:

- ◆ Child's name
- ◆ Child's sex
- ◆ Child's date of birth
- ◆ Child's NHS number
- ◆ Your mobile number and/or email address

People who do not need to know your child's name or contact details will not be able to see them. Your child's data will have an anonymised participant ID number instead. The sponsor (University of Birmingham) will keep all information about your child safe and secure. Once we have finished the study, the sponsor will keep some of the data for 25 years so they can check the results. Your child's personal details and your contact details will be deleted after the study finishes and any central NHS data has been collected. The sponsor will write the reports in a way that no-one can work out that your child took part in the study.

All information about your child and their health will be kept confidential. The only people allowed to look at your child's information will be the doctors and research staff who are running the study, authorised staff at University of Birmingham and your hospital, and the regulatory authorities who check that the study is being carried out correctly. A privacy notice is on the study website: [[www.birmingham.ac.uk/privacy/index.aspx](http://www.birmingham.ac.uk/privacy/index.aspx)].

If you agree, we would also like to use the data we collect to support other related research in the future. This could include sharing the data anonymously with other researchers, but this will only be done if you have given your permission.

If you consent to it, the researchers involved in the study may, in future, access data from your child's central NHS records, for example through NHS Digital. This will give researchers information that is already collected during GP and hospital visits, and lets researchers find out about your child's health after the study has ended without needing to contact you again. To do this, we would send your child's name, sex, date of birth and NHS number with any request for information. If you don't want us to do this, just let the research team know.

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**11. Who is involved with the study?**

The study is sponsored by the University of Birmingham which means the University of Birmingham has certain legal and ethical responsibilities for the study. It is being coordinated by Birmingham Clinical Trials Unit. The Chief Investigator for the study is Dr Stuart Hartshorn, who is a Children’s Emergency Medicine Consultant at Birmingham Children’s Hospital. The study is being funded by the Department of Health through the National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme (ref: NIHR134534) and is the work of children’s Emergency Doctors across the UK.

The research team has a lot of experience in caring for children and young people with infections. They are also involved in research studies that can improve care and health in children.

**How have patients and the public been involved in this study?**

For this study, two groups of parents and young people helped to decide which results are important to patients, families and carers. They also helped us decide how and when the site should follow-up children. A parent from one of the groups is part of the study team.

**Who has reviewed the study?**

The study has been reviewed by independent doctors and scientists on behalf of the funders. It has been approved by the body that regulates medicines in the UK, the Medicines and Healthcare products Regulatory Agency (MHRA). A Research Ethics Committee has reviewed the study documents to protect participants’ safety and dignity. This study has been reviewed and given a favourable opinion by [add name of REC].

**What if something goes wrong?**

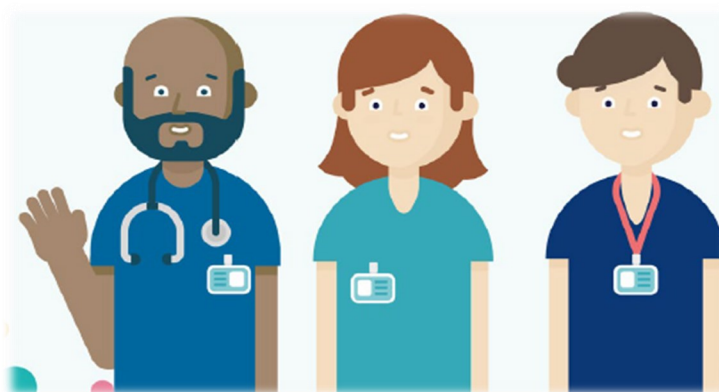
We do not expect any problems to occur because of your child taking part in the trial. However, all participants are covered for negligent harm according to NHS indemnity guidelines.

If you or your child have concerns about any aspect of this trial, you should ask to speak to a member of the research team who will do their best to answer your questions.

If this hasn’t resolved your concern, and you wish to complain about any aspect of the way you or your child have been approached or treated during this trial, the normal NHS complaints mechanisms will be available to you. Your child’s hospital Patient Advice and Liaison Service (PALs) team will be able to help you with this.

Tel:

Email:



**12. What happens at the end of the study?**

The sponsor will publish the results in a medical journal, so that other doctors can see them, and will also send them to groups that agree guidelines for treatment of children.

Parents who have helped design this study will help deliver the final message to parents and children. A summary of the results will be published on the study website (curly.digitaltrial.com) so you can see them.

No named information about your child will be published in any report of this study.

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**13. Where can I find out more about how my child’s information is used?**

**Who is the data controller?**

The University of Birmingham, Edgbaston, Birmingham B15 2TT is the data controller for the personal data that is processed in relation to your child. This means that the University is responsible for looking after your child’s information and using it properly.

**What are my choices about how my child’s information is used?**

You can stop being part of the trial at any time, without giving a reason, but we will keep information about you that we already have. The sponsor needs to manage this data in specific ways for the research to be reliable and accurate. This means that they will not be able to let you see or change the data the sponsor holds.

More information on how the University processes personal data can be found on the University’s website on the page ‘Data Protection – How the University Uses Your Data’ (<http://www.birmingham.ac.uk/privacy/index.aspx>).

**How will my child’s personal data be kept secure?**

The University of Birmingham takes great care to ensure that personal data is handled, stored and disposed of confidentially and securely. Staff receive regular data protection training and the University has put in place organisational and technical measures so that personal data is processed in accordance with the data protection principles set out in data protection law.

In relation to this project, any physical paperwork containing identifiable data will be kept in an access-controlled and secured room inside a locked filing cabinet. Electronic data will be kept on secure, encrypted IT servers within the University of Birmingham.

**Where can I find out more about how my child’s information is used?**

At [www.hra.nhs.uk/information-about-patients/](http://www.hra.nhs.uk/information-about-patients/)

In the leaflet available from [www.hra.nhs.uk/patientdataandresearch](http://www.hra.nhs.uk/patientdataandresearch)

By asking one of the research team

By contacting the Data Protection Office, Legal Services, The University of Birmingham, Edgbaston, Birmingham B15 2TT

Email: [dataprotection@contacts.bham.ac.uk](mailto:dataprotection@contacts.bham.ac.uk)

Telephone: 0121 414 3916



**STUDY CONTACTS**

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