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**NATIONAL CHILDREN'S  
RESEARCH CENTRE**

The National Children's Research Centre (NCRC) is a charitable organisation and the largest paediatric research facility in Ireland. It supports investigations into the cause, diagnosis, treatment and prevention of childhood illness and injury, through a series of research grants to principal investigators (senior doctors and scientists) and through an MD/PhD/MSc academic training programme. The NCRC is funded by the Children's Medical Research Foundation (CMRF).  
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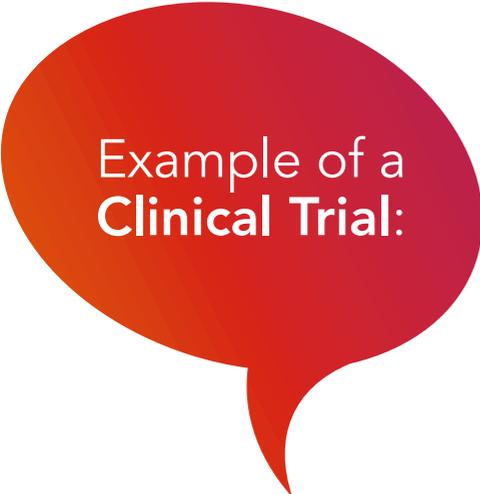
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**NATIONAL CHILDREN'S  
RESEARCH CENTRE**

## An Example of a Clinical Trial GIRLS





## Example of a Clinical Trial:



**Kate is an 8 year girl from Mayo** who loves Irish dancing and playing with her younger brother Alan. Kate has a dry-skin condition called eczema (pronounced “ek-suh-muh”). This hasn’t been getting better and her GP doctor makes an appointment for her to see a specialist skin doctor, called **Maeve**, in a hospital.

When she goes to the hospital, **Doctor Maeve** examines Kate and tells her and her Mum about a clinical trial that some of her patients are taking part in. It involves children with eczema between the ages of 2 and 12 years old of age.

The clinical trial is studying two different creams used to treat eczema, one which has already been used by doctors for a few years and a new one which has just started to be used. The doctors aren’t sure if one cream works better in children and have designed a clinical trial to try to find out.

**Doctor Maeve** gives Kate’s Mum information about the study to read.

**Doctor Maeve** then tells Kate about the kind of checks the study will involve:

- examining the skin
- taking measurements of height and weight
- asking a few questions about food and how much time is spent in the sun
- taking a small blood sample

**Doctor Maeve** tells Kate that if she takes part, she will have some of the checks today and will then use one of the creams every day for three weeks.

**Doctor Maeve** will phone Kate’s Mum one week later to check if Kate has had any problems; Kate and her Mum will then come back to the hospital for a check-up two weeks later.

Kate and her Mum have time to ask any questions about the study. Kate asks if the cream stings and **Doctor Maeve** says that it doesn’t sting at all but it is a bit thick and can take a while to dry. Kate asks if she has to take part and **Doctor Maeve** tells her that she doesn’t have to take part in the study and that no one will be upset with her if she doesn’t want to.

Kate’s Mum asks questions about the different creams that can be used to treat eczema and **Doctor Maeve** answers them all. Kate and her Mum decide to take part in the clinical trial.

Kate’s Mum signs a form to show that the clinical trial was explained in detail and that she gave her permission for Kate to take part. This is known as the **CONSENT FORM**.

Kate signs a form to show that the clinical trial was also explained to her and that she wanted to take part as well. This is known as the **ASSENT FORM**.



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**Doctor Maeve** then examines Kate’s skin, and asks Kate and her Mum if there are any foods that Kate eats that make her feel sick or unwell and how much of the day she spends playing outside. **Doctor Maeve** records all of this information in her medical chart and study forms. **Doctor Maeve** would have done this as part of Kate’s normal medical care, even if Kate wasn’t taking part in the clinical trial.

**Doctor Maeve** then explains to Kate and her Mum which one of the creams she will get and how to use it. A certain number of children will be given the first cream and the rest of the children will be given the second cream.

Kate is given the second cream and **Doctor Maeve** shows Kate and her Mum how to use it.

Kate then has a small blood test. Kate feels a pinch in her skin for a few seconds when the blood test is being taken. A small bruise might develop but it will fade after a few days.

At the end of the visit, Kate and her Mum are both given copies of the **CONSENT** and **ASSENT** forms that they signed and are asked to come back to the hospital in three weeks time.

**Doctor Maeve** phones Kate’s Mum one week later to see how Kate is getting on. Kate and her Mum come back to the hospital for a check-up two weeks after that.

**Doctor Maeve** examines Kate’s skin and explains the blood test results to Kate and her Mum. **Doctor Maeve** asks Kate and her Mum how she was feeling over the last three weeks. Kate says that she felt pretty good but had a tummy upset last week. **Maeve** makes a note of this in her medical chart and study forms.

That is the end of Kate’s involvement in the clinical trial.

Kate continues to see **Doctor Maeve** for her regular check-ups.

**Doctor Maeve** continues to ask other children to be involved in the study.

When the study is finished, normally because enough children have tried the two different creams, the doctors will have a better idea which cream works the best. This will all help to better look after girls and boys who have eczema.

**Kate still loves Irish dancing.**