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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).
www.nationalchildrensresearchcentre.ie

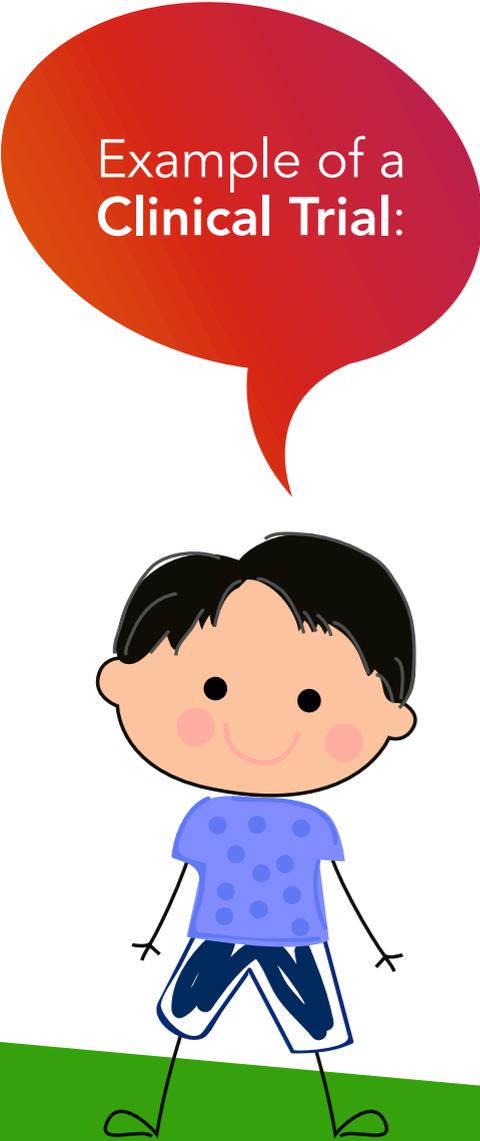
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**NATIONAL CHILDREN'S
RESEARCH CENTRE**

An Example of a Clinical Trial BOYS





Example of a Clinical Trial:

John is an 8 year boy from Galway who loves playing hurling and playing with his younger brother Cathal. John has a dry-skin condition called eczema (pronounced "ek-suh-muh"). This hasn't been getting better and his GP doctor makes an appointment for him to see a specialist skin doctor, called **Maeve**, in a hospital.

When he goes to the hospital, **Doctor Maeve** examines John and tells him and his Mum about a clinical trial that some of her other patients are taking part in. It involves children with eczema between the ages of 2 and 12 years 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 John's Mum information about the study to read.

Doctor Maeve then tells John about the kind of checks the study will involve such as:

- 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 John that if he takes part, he will have some of the checks today and will then use one of the creams every day for three weeks.

Doctor Maeve will phone John's Mum one week later to check if John has had any problems. Then John and his Mum will come back to the hospital for a check-up two weeks later.

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

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

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

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

Doctor Maeve then examines John's skin, and asks John and his Mum if there are any foods that John eats that make him feel sick or unwell and how much of the day he 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 John's normal medical care, even if John wasn't taking part in the clinical trial.

Doctor Maeve then explains to John and his Mum which one of the creams he 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.

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

John then has a small blood test. John feels a pinch in his 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, John and his 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 John's Mum one week later to see how John is getting on. John and his Mum come back to the hospital for a check-up two weeks after that.

Doctor Maeve examines John's skin and explains the blood test results to John and his Mum. **Doctor Maeve** asks John and his Mum how he was feeling over the last three weeks. John says that he 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 John's involvement in the clinical trial.

John continues to see **Doctor Maeve** for his regular check-ups.

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

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

John still loves playing hurling!



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