

Information Sheet for Person with Parental Responsibility Northern Ireland Caries Prevention in Practice (NIC-PIP) Trial

Introduction

In Northern Ireland two thirds of 5-year-old children have tooth decay (the technical name for which is dental caries) in their baby teeth. This commonly results in toothache and teeth being extracted, many under general anaesthetic in hospital. In Northern Ireland a quarter of 2-3-year-olds already have tooth decay when they first visit their dentist, but worryingly half of children who are free of tooth decay at their first visit go on to develop the decay over a 3 year period, even though they attend the dentist regularly. A team from the Health and Social Care Trusts in Northern Ireland, dentists working in general practice, community dentists and researchers from the University of Manchester want to undertake some research to see if we can improve this situation.

What is the purpose of the study?

We want to undertake a research project to see if dentists can prevent tooth decay in young children by painting a fluoride varnish on the teeth twice a year for a three year period plus giving a toothbrush and family strength fluoride toothpaste to children twice a year. We also want to find out how cost effective this might be.

Why has my child been chosen?

Your family dental practice has agreed to work with us and children aged 2 and 3 years old attending the dental practice will be invited to take part in the study. The research concentrates on preventing tooth decay, so children who already have tooth decay or fillings will not be invited to join the study.

What will happen to my child if they take part?

At your child's next routine dental examination with their own dentist a dentist from outside your practice will explain the study in detail and ask you to confirm your consent for your child to participate. They will then perform a simple dental examination to check that there is no tooth decay. Children eligible to take part in the study will be randomly placed into one of two groups. (chosen by computer with an equal chance of being placed in either group). One group will receive fluoride varnish, toothpaste and toothbrush, plus standard dental health education. The other group will receive the standard dental health education alone.

Children will attend for routine check ups every 6 months, and we will ask you, whichever group your child is in, to complete a short questionnaire each time you bring your child to the dentist. This is to collect information on how far you have travelled to the dentist and if your child has experienced any dental or other health problems. For those in the group receiving the fluoride treatment, fluoride varnish will be applied at each check up by your dentist using a small disposable brush and a toothbrush and toothpaste will also be given out with standardised dental health education. The other group will receive the dental health education alone. If your child requires any additional dental care during this time, it will be carried out by your dentist as normal.

The study ends 3 years later when a dentist from outside your practice will return to perform another simple examination. The results from the two groups will be compared.

Does my child have to take part?

Taking part in this study is entirely voluntary and you are free to withdraw your child at any time even after you have provided consent for them to be involved. Deciding not to take part in this study will not affect your child's eligibility for dental treatment in any way now and in the future. Before the first examination, you will be given the opportunity to withdraw your child from the study if you do not wish to take part.

What are the side-effects of any treatment received when taking part?

The varnish used in the study has been widely used across the world for many years and any side-effects to the varnish are extremely unlikely to occur and would be very mild if they do.

In addition to fluoride, the varnish contains ethanol and a natural resin called colophony, which is found in Elastoplasts. This can, on rare occasions, lead to localised reddening of the gums. In highly exceptional circumstances, use of colophony has resulted in allergic reactions and for this reason we are excluding all children who have been hospitalised due to severe asthma or other allergic conditions.

Another possible side effect is dental fluorosis which may occur and which affects adult teeth. In its mildest form dental fluorosis appears as fine white lines or flecking on the enamel surface of the teeth, which can often only be detected by a dental expert.

Fluorosis which is noticeable to ordinary members of the public can arise if too much fluoride is swallowed by very young children, but as only a small amount of fluoride varnish is applied, it will be applied by dentists and clear instructions will be given to you about how your child should use fluoride toothpaste the risk of this occurring is very low.

In the unlikely event that something does go wrong and your child is harmed during the research due to someone's negligence, you may have grounds for a legal action for compensation but you may have to pay your legal costs. You will also be able to use the normal Health and Social Care complaints service.

The University of Manchester also has insurance for no fault compensation for where an injury resulted from the trial or procedure received as part of the trial. This would be subject to policy terms and conditions and any payment would be without legal commitment. (Please ask if you wish more information on this). The University would not be bound to pay this compensation where the injury resulted from a drug or procedure outside the trial procedures or where the procedures were not followed.

We have also set up an independent committee, who will monitor any reported side effects and will stop the study early if they think there is any risk to the children participating in the study.

What if there is a problem?

We will provide you with an information card if your child is recruited onto the study with trial contact details of who and where to contact, should you have any questions or concerns. You should ask to speak to the researchers who will do their best to address any concerns. If they are unable to resolve your concern or you wish to make a

complaint regarding the study, please contact Belfast Health and Social Care Trust on 02890630023. If you would like independent information about participating in research please contact your local Patient and Client Council.

What will happen to any information collected during the study?

Information we collect includes your child's name, date of birth and postcode, detailed information about their teeth and information from you about whether your child experiences any side effects or toothache. All information about individuals involved will remain confidential but may be made available to the study sponsors (The University of Manchester and the Belfast Health and Social Care Trust) or regulatory authorities responsible for clinical trials in the UK (the Medicines and Healthcare products Regulatory Agency). If information is used in scientific publications no individuals will be identified. All this information can be made available to you at your request.

If you require any further information please contact your practice or a member of the research team at the Clinical research Support Centre on 02890633523.

Yours sincerely

Michael Donaldson
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This trial is co-sponsored by Belfast Health and Social Care Trust and the University of Manchester

*The research to be carried out has been approved by an
NHS Research Ethics Committee and the Research Ethics Committee of the University of Manchester.
This does not imply any endorsement.*