Total Daily Fluoride Intake and Excretion in Infants aged 0 to 12 months

Study Information Document (Parents/Guardians)

School of Health and Social Care
University of Teesside
Middlesbrough
What is this Study Information Document (SID) for?

This SID provides information regarding this study and invites you to take part in this research project.

Who is doing the research?

This project is being carried out at the School of Health and Social Care at Teesside University by Dr Vida Zohoori in collaboration with Professor Anne Maguire and Dr Ruth Valentine, from the Centre for Oral Health, School of Dental Sciences, Newcastle University. Teesside University is the study sponsor and the project is funded by the Organix Foundation.

What is being researched?

We are trying to estimate total daily fluoride intake and excretion of infants in the UK. In the UK approximately 12% of the population receive fluoridated tap water, either naturally present or artificially adjusted. We therefore wish to compare the amount of fluoride an infant retains in her/his body when living in a fluoridated area, with a non-fluoridated area.

Why are we researching this, and what are the benefits?

Fluoride has an important role in developing and maintaining healthy teeth, especially during the first years of life. It is found naturally in foods that we consume, in water that we drink, as well as in most toothpaste that we use. Fluoride at low concentrations helps protect teeth against dental decay. However ‘discoloration’ or mottling of teeth can occur if young children are exposed to excessive levels. Therefore regular monitoring of fluoride intake has been recommended by many organisations including the World Health Organisation.

Collection the urine produced over twenty-four hours has been suggested as the best way of assessing recent exposure to fluoride since the major route for the removal of fluoride taken in by the body is by the kidneys, while it has been estimated that 5 to 10% of ingested fluoride is excreted with faeces. However, kidney function is not fully developed at birth and it is important when any recommendations are being made about fluoride use in infants and young children that these are based on good knowledge of the proportion (or fraction) of fluoride intake that is retained in the body. In addition to the urine, fluoride concentration in fingernail clippings has also been suggested as a useful marker for fluoride exposure over time. Since, within the UK some areas receive fluoridated water, and others receive non-fluoridated water, it is important to measure the amount of fluoride that infants in these areas take in through foods, drinks and toothpastes. This will provide valuable information for future research designed to answer questions about fluorides, and may help to develop recommendations for programmes to reduce dental decay in young children.
Can you participate?

You can take part in the study if you are pregnant or are a legal parent (biological or other) or guardian of an infant who is:

- Between 0-3 months;
- Has no dietary restrictions;
- Has good general health;
- Has been living in either Newcastle or Middlesbrough since birth.

However, you cannot take part if your infant is:

- Taking any medicines;
- Has a restricted diet;
- Has gastrointestinal, bone, renal problems or a history of urinary tract infections;
- Has any other illness such as a chest infection, temperature, etc.

What will happen if you decide to take part?

The study is carried out in two stages: during pre-weaning when your baby is between 0-3 months old and post-weaning when your baby is older than 9 months of age.

If you decide to take part, at each stage you will be asked to:

1) Keep a three day food diary for three consecutive days (two weekdays and one weekend day), of all the food and drink your infant consumes.

2) Provide samples of any homemade food or drinks that your infant consumes over those 3 days for fluoride analysis.

3) Provide a sample of breast milk if your baby is breast-fed, Providing this sample is entirely voluntary.

4) Collect urine samples from wet nappies, using sterile urine collection packs which are provided for you.

5) Collect all used nappies in separate plastic bags which are provided for you and record the time of each collection in a diary which is provided for you.

6) To clip fingernails of your infant and keep those in separate zip lock bags that we provide for you.

Will you need any special equipment?

We will provide you with all the equipment you need, as well as clear instructions on how to collect the information we need.

What about the three day food diary?

We will provide you with a special diary to record the food and drink your infant consumes, with full instructions of how to fill in the diary. You will not be required to weigh the foods, just give us an idea of the size of the portion by writing it down in the diary, e.g. one small cup of tap water, one mashed medium-sized banana.
We would arrange to meet with you on the 4th day to check that everything has been recorded clearly and thoroughly and collect used nappies from you.

**How do I measure the amount of breast milk my infant has consumed?**

If you are breast feeding your infant we understand that it is difficult to know how much milk they have consumed. However, since babies self regulate their feeding, we would be able to estimate breast milk consumption by your baby by using the number of feedings per day and the how long each feed lasts, based on your recording in the food diary.

**What about food samples?**

We will need to take samples of any homemade food or drink that your infant consumes over three days including a sample of breast milk, but will require only a small sample (about one tablespoon). We will then analyse these samples for fluoride concentration.

We will give you full instructions and a demonstration on how to provide samples, as well as provide containers for this food drink and breast milk samples and will collect them from you.

From our ongoing research, we already have access to information about the fluoride content of common ready-to-feed infant foods and drinks, so it will just be samples of any homemade foods and drinks as well as breast milk that we will request from you.

**What about urine collection pads?**

Urine collection pad is an absorbent pad used in medical practise for collection of urine from infants and non-toilet trained children. Urine collection pads are made of plain cotton fibre to facilitate extraction of urine. They are sterile, safe, easy to apply and do not interfere with the routine care.

You are provided with Newcastle sterile urine collection packs (Ontex Ltd, Corby, Northamptonshire UK, NHS Supplies). Each pack contains two pads, a sterile syringe and container. Instruction on how to use the pads will be provided for you.

**What about urine samples?**

Each time that you change your child’s nappy, if it is wet you are required to extract 3-5 ml urine from the wet pad and transfer it into the container. You should also keep the wet nappy/pad separately in a plastic bag and label bag and bottles and plastic bags. We will provide you with full instruction on how to extract urine.

We will collect urine samples and wet nappy/pads from you. All the urine samples will be stored at -20°C with a restrict access (see below) until they are analysed for fluoride.

**What about soiled nappies and fingernail clipping?**

All the soiled nappies will be ashed at 600°C and the fluoride concentration of these ashed samples as well as fingernail clippings will be measured.
What about storage and disposal plan for the samples?

All the samples collected from your baby will be labelled with a unique ID number which is not identifiable. The samples will be kept in research laboratory, in the School of Dental Sciences, Newcastle University, where access is restricted to members of the research team. The samples will be retained until the outcome of the research is published. They will then be incinerated and disposed according to the University’s waste disposal system.

Do we need any other information?

Yes, we will also be asking about your infant’s tooth brushing habits, and record their gender, weight and date of birth.

Will the information be kept confidential?

Yes, you and your infant’s details will be kept confidential. All information collected as part of this study will be stored in accordance with the Data Protection Act (1998) unless anyone involved in the study should appear to be at risk of harm. If any abusive or unprofessional behaviours or actions are disclosed and/or discovered then confidentiality will be breached and the supervisor will be informed (in the first instance) and, if deemed appropriate, further actions may be taken.

To maintain the confidentiality and anonymity, you will be given a unique ID number on the consent form and information sheet. Your/your infant’s name will not be recorded with the data collected. Any paper-based materials you may give us will be stored in a locked filing cabinet for the length of the project, and/or stored electronically on password-protected computers at Teesside University. Access to the study materials and data, while the study is underway, will be restricted to members of the research team. After the project is completed all the study materials and information will be stored securely for up to six years by Teesside University and then destroyed.

What is your involvement?

The study is in two stages and each stage includes two visits as follow:

Visit one: we will visit you in your home or a mutually convenient location to; a) record date of birth, place of residency and gender; b) help you measure the weight of the infant, and; c) obtain information on tooth-brushing habits (if you brush your child’s teeth) such as type of regularly used toothpaste, starting age of using a toothpaste, brushing frequency per day.

You will be provided with the food diary, nappy diary, urine collection packs (containing syringe, bottle and pad) and appropriate containers to collect food and drink samples as well as wet/soiled nappies and fingernail clippings. We will explain to you in detail how to complete the diaries and collect samples, and answer any questions that you have.

Visit two: We will visit you again after you have collected urine samples and completed both food and nappy diaries to collect the diaries and samples. At this visit we will go through the diaries with you to make sure that we have all the necessary information.
Do you have to take part?

No; your participation would be entirely voluntary. If, after receiving the information about the study you agree to take part you will be asked to sign a consent form. You can withdraw from the study before data collection started, without giving reason. To withdraw from the study please call the researcher (Dr Narges Omid - see contact details below), and quote your ID number (found at the top of your consent form and information sheet). However, you cannot withdraw your child’s data from the study after completing the second stage of the study.

Do you need more information before taking part in the study?

If you have any further questions do not hesitate to contact a member of the research team, who will be happy to answer any questions that you have.

Finally...

We do understand that this study involves quite a lot of input from you, as well as the inconvenience of collecting food samples and used nappies. Therefore we would like to thank you at the end of the study by providing you with a £50 gift voucher.

Do you have any questions after taking part in the study?

If you have any questions or concerns about any aspect of the study, you can call Dr Narges Omid (n.Omid@tees.ac.uk, Research Mobile no: 07535118024) who will be happy to answer any questions you might have. Should you still have any concerns, you can contact Dr Vida Zohoori on 01642342973 at the School of Health and Social Care, Teesside University.

For independent advice, you may contact Dr Alasdair MacSween at Teesside University. Dr MacSween knows about the study but is not involved in it:

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