



PAPA Information for Parents & Carers – Is the Study Right for Your Baby?

Preventing childhood Asthma using Prophylactic house dust mite Allergen immunotherapy



You are being invited to consider including your child in the PAPA trial. For more information please see our website:

<https://papastudy.uk/>

This study is looking at whether giving babies and young children a daily dissolvable tablet containing a tiny amount of house dust mite protein could help prevent asthma.

Asthma is a common condition in children and currently there is no way to prevent it.

This study
aims to recruit

434

babies

across the
UK

What is asthma and why is it a problem?

- Asthma causes wheezing, coughing and/or tightening of the air passages which can be relieved with medication.
- Asthma affects more than **1 million children** in the UK. There is no cure, but it may be possible to prevent asthma.
- Most children in the UK with asthma are allergic to house dust mite (HDM).

What is the purpose of the trial?

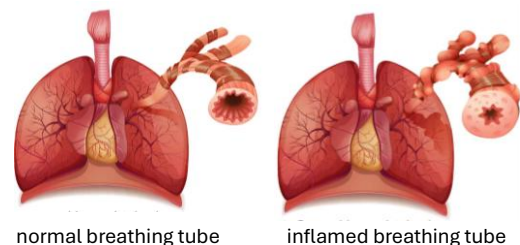
- We know that if babies are given peanut butter or egg to eat when they are young, they are less likely to develop allergy to peanut or egg.
- We want to test whether using a similar approach with HDM protein might stop babies developing allergy to HDM and asthma.

Why might my child be suitable for this study?

Your child:

- Is between 5 and 12 months old.
- Is at higher chance of developing asthma. This is because there is a family history or your child has eczema.

Asthma – Inflamed Breathing Tube



What will happen if we take part in the initial screening?

You are expressing interest in hearing more about the PAPA trial. **You are not consenting to taking part in the PAPA trial at this stage**, just to be contacted for more information.

If you are happy to be contacted about this research:

- we will ask you to complete a short online questionnaire (take around 5-10mins) about **your child's health, biological siblings, their parents, history of allergies and asthma**
- collect your contact details in order to be contacted by a member of the research team for more information.

If answers to your questionnaire indicate your child is suitable, a member of the research team will be in touch to discuss the trial further and invite you to a check-up at your hospital clinic. If you were invited through your child's GP practice, we will ask for your preferred hospital before completing the questionnaire.

Do I have to take part?

- No, it is your choice.
- If you decide to take part, you are free to withdraw your child at any time and without giving a reason.
- A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care your child receives.



Will my child's details and information be confidential?

All of you and your child's personal details will be kept in a pseudonymised format and confidential.

This means a **code number** will be used instead of your name and only your care team can link the code with your details.

We will collect your contact details (name, address, email, telephone number) in order to contact you with further information if your child is suitable.



Who is organising and funding the trial?

- Organised and run by researchers at the University of Southampton and Imperial College London.
- The main Investigator of the trial is Professor Syed Hasan Arshad.
- Funded by the National Institute for Health Research.
- Sponsored by University of Southampton.

Contact Details

If you wish to ask any questions or speak to a member of the research team:

Name: [name of doctor and/or nurse]

Telephone number: [phone number]

Email: [email]

If you are unhappy or have a complaint about any aspect of this study, please contact the University of Southampton Head of Research Ethics and Governance details:

Telephone: 023 8059 5058. Email: rgoinfo@soton.ac.uk