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TRANS-FOODS: Reducing the risk of developing peanut allergy through the skin by improved understanding, modifying peanut snack production, and adjusting skincare practices.

Submission date
11/09/2023

Recruitment status
No longer recruiting

Registration date
25/09/2023

Overall study status
Ongoing

Last Edited
03/02/2025

Condition category
Skin and Connective Tissue Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Allergic diseases, including atopic eczema, and food allergies affect over a quarter of all children across Europe. The way the immune system responds to ingested foods are well-established, and regular eating of allergy-causing foods can prevent food allergies to a degree. However, recent research also shows that food allergies can develop through the skin, especially in the presence of dry skin and eczema. We do not fully understand how this happens at the moment.

This project aims to study the immune responses to peanut allergen in those with a skin barrier defect with and without skin massage.

Who can participate?
Anyone without a history of peanut allergy.
Anyone either with a history of dry skin/eczema or healthy skin.
Anyone aged 18 years or over.

What does the study involve?
60 healthy adult volunteers and 60 adult volunteers with atopic dermatitis and dry skin will be asked to either massage, or not massage the skin after applying peanut extract twice daily for 4 weeks at home. Half of the participants will also apply a barrier enhancing cream 30 minutes before applying the peanut extract.

Samples of interstitial fluid (ISF) will be collected from the same location that the cream and peanut extracts are being applied and at another site that is remote to this site during a visit to King's College London. The amount of water that evaporates from the skin will be measured with a small hand-held machine. A chamber will then be placed on your forearm and a small volume of water will be applied. A hand pump will be used to apply suction on your forearm for about 10 minutes at a pressure we know will not damage the skin. The suction will pull molecules called cytokines out of the skin and we will remove the liquid from the skin containing

these cytokines using a plastic pipette. The extracted samples will be collected for analysis of the extracted chemicals.

Participation in this study will require presence in two extraction sessions with an interval of 4 weeks, each session will last for approximately 1 h.

What are the possible benefits and risks of participating?
The participants will be tested to peanut and environmental allergens. Otherwise, there is no direct benefit, however, the scientific information that is obtained from this research will be used to help scientists and doctors learn more about the causes of peanut allergy and could benefit people in the future.

There is a very low risk of an allergic reaction to the skin prick test or the peanut preparation used in this study. The use of the interstitial fluid device may result in the formation of a transient indentation mark on the skin caused by the suction chamber. Bruising may occur with the use of this device, which should go away after a couple of days.

Where is the study run from?
The study is run from King's College London

When is the study starting and how long is it expected to run for?
July 2022 to May 2026

Who is funding the study?
1. Biotechnology and Biological Sciences Research Council (UK)
2. Food Standards Agency (UK)
3. Joint Programming Initiative (UK)

Who is the main contact?
If you have questions about this research study, contact the research team via email TransFoods@kcl.ac.uk

Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
NCT05407012

Secondary identifying numbers
Nil known

Study information

Scientific Title
TRANS-FOODS: Preventing Peanut Allergy Through Improved Understanding of the Transcutaneous Sensitisation Route, Novel Food Processing and Skin Care Adaptations (TRANS-FOODS)

Acronym
TRANS-FOODS

Study objectives
1. When a peanut protein-containing solution is regularly massaged into the skin, peanut protein components can be detected in ISF.
2. Higher concentrations of peanut protein are detected in ISF in those with skin barrier impairment (dry skin and AD).
3. Peanut proteins present in ISF retain their allergenicity and can interact with immune cells and induce activation of blood basophils and mast cells from peanut-allergic donors.
4. Regular skin massage with peanut protein extract induces detectable skin inflammation (raised Th2 cytokines, TSLP, and IL-33), more so in those who have dry skin and AD/raised TEWL at baseline (compared to no massage).
5. The cutaneous uptake of peanut protein is attenuated by the prior application of a barrier-enhancing moisturising cream.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 23/06/2023, KCL REC (3rd Floor, 5-11 Lavington Street, London, SE1 0NZ, United Kingdom; -; rec@kcl.ac.uk), ref: HR/DP-22/23-37419

Study design
Pilot investigational interventional randomized parallel open label

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Home, Laboratory, University/medical school/dental school

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Peanut allergy and atopic dermatitis

Interventions
Using block randomisation, the two groups of healthy volunteers and participants with skin barrier impairment (AD/dry skin) will be evenly split into the following groups:
- application of the barrier enhancing preparation around 30mins before application of the peanut protein extract +/- massage after extract application
- no application of the barrier enhancing preparation, just application of the peanut protein extract +/- massage after extract application

This will generate 8 intervention groups of 15 participants each. Participants will apply the test interventions to the central area of the left outer forearm twice daily with 10 mins massage throughout the 4-week study period. The control semi-solid formulation (containing no extracts) will be applied without massage to the central right outer forearm twice daily as control. We will provide detailed instructions for all participants on the following:
-hand hygiene prior to the application of the study intervention (left outer forearm) and the sunflower oil control (right outer forearm),
-clear instructions on how the massage is to be performed (if participants are randomised to this intervention) to standardise this across participants. Participants will follow the massaging technique at home using video guidance, which we will send to the participant at the start of every week as a reminder, and
-that no other topical preparation must be applied for at least 4 hours after the application to allow for take up into the skin. (This is based on our extensive experience in studying topical preparations and to avoid cross-contamination and ensure adequate cutaneous uptake of the peanut extract).

Intervention Type
Other

Primary outcome measure
1. Detection of peanut protein components (µg of the proteins per cm^2 of skin) in retrieved interstitial fluid. [Time Frame: 8 weeks]
2. Activation of blood basophil/mast cell from peanut allergic donors (measured as %CD63-positive basophils/mast cells) by peanut proteins present in interstitial fluid. [Time Frame: 8 weeks]

Secondary outcome measures
1. Detection of inflammatory cytokine markers (IL-4, IL-13, IL-33 and TSLP) in interstitial fluid. [Time Frame: 8 weeks]
2. Raised transepidermal water loss. [Time Frame: 8 weeks]

Overall study start date
07/07/2022

Completion date
31/05/2026

Eligibility

Key inclusion criteria
1. Adult healthy volunteers (50% of the cohort), and adults with dry skin and AD (fulfilling the refined Hanifin and Rajka criteria, 50% of the cohort).
2. Written informed consent for study participation.
3. Competent use of English language.
4. Willingness to comply with all study requirements.

Participant type(s)
Healthy volunteer, Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
120

Key exclusion criteria
1. Patients unable to give informed consent.
2. History of peanut allergy.
3. Positive skin prick test to peanut (>0 mm).
4. No regular consumption of peanut products.
5. Widespread AD, in particular if this involves the test sites of the forearms.

Date of first enrolment
05/04/2024

Date of final enrolment
31/07/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
King's College London, Franklin-Wilkins Building.
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Sponsor type
University/education

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ROR
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Funder(s)

Funder type
Research council

Funder Name
Biotechnology and Biological Sciences Research Council

Alternative Name(s)
UKRI - Biotechnology And Biological Sciences Research Council, BBSRC UK, BBSRC

Funding Body Type

Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Food Standards Agency

Alternative Name(s)
The Food Standards Agency, FSA

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Funder Name
Joint Programming Initiative

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/01/2027

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from TransFoods@kcl.ac.uk.

IPD sharing plan summary
Available on request