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Soya lecithin and non-IgE soya allergy

Submission date
31/07/2019

Recruitment status
No longer recruiting

Registration date
20/08/2019

Overall study status
Completed

Last Edited
18/03/2020

Condition category
Injury, Occupational Diseases, Poisoning

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
The impact of a food allergy is not just on the child and their immediate family but beyond that, due to the anxiety and stress it causes while trying to avoid contact of the child with the allergen. Children that have IgE, non-IgE or mixed symptoms to soybeans are recommended to avoid it in all its forms. Soya lecithin is extracted from soybean oil and it is used in the industry for the structure and the texture of many processed foods, but not more than 1% of soya lecithin is used in these foods. The limited studies that were published show that soya lecithin does not cause reactions in the IgE allergic child, but it has never been reviewed in the non-IgE soya allergic children. The aim of this study is to investigate allergenicity in non-IgE soya allergic children, because the elimination of soya lecithin from the diet of multiple allergic children limits their food choices significantly.

Who can participate?
Children between 8 months and 5 years of age with non-IgE soya allergy

What does the study involve?
Participants are randomly allocated to eat either a soya lecithin or non-soya lecithin containing biscuit daily for 1 week. This is followed by 1-week break before switching to the other biscuit for 1 week. The amount of soya lecithin in the biscuits is relative to the quantity found in processed foods sold in stores. The challenge foods are produced by DuPont Nutrition & Health (Solae, LLC), St. Louis, MO), USA. Both soya lecithin and placebo challenge foods are packaged in separate sealed coded envelopes (daily dosage within each container) and coded according to the random allocation. Symptoms are recorded before starting the study and at the end of each week. Questionnaires are filled out by parents at the start of the study and at the beginning of each week, and parents immediately report any complications caused during the 3 weeks. The gastroenterologist, dietitian and researcher on the case deal with problems if they occur. If parents report a reaction after week 1, the researcher is contacted and the researcher can extend the break if the reaction is deemed to be severe.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Great Ormond Street Hospital for Sick Children NHS Trust (UK)

When is the study starting and how long is it expected to run for?
January 2014 to February 2015

Who is funding the study?
DuPont Nutrition & Health (USA)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nr.14/LO/0746

Study information

Scientific Title
Tolerance of soya lecithin in children with non-IgE mediated soya allergy: a randomized double-blind cross-over trial

Study objectives
Soya lecithin is present in a wide variety of foods regularly consumed by children, as an emulsifier or stabilizer. Children with non-IgE mediated allergies who commonly have to avoid

milk and soya will have a significantly restrictive diet with reduced alternative foods, if soya lecithin also has to be eliminated. The objective is to establish if children with non-IgE mediated gastrointestinal soya allergy react to soya lecithin in food products.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/05/2014, NHS Health Research Authority- London, Bromley (Skipton House, 80 London Road, London,
SE1 6LH, UK; Tel: +44 (0)207 104 8019; +44 (0)207 104 8209; Email: nrescommittee.london-bromley@nhs.net), REC ref: 14/LO/0746

Study design
Double-blind randomised cross over study

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Non-IgE mediated soya allergy in children

Interventions
A double-blind cross over study was performed in soya allergic children aged between 8 months-5 years. Eligible children had their soya allergy status confirmed with a home challenge. Children were randomly assigned to either placebo or challenge dose of soya lecithin (1.5 g per day) in a custom-made biscuit. This was followed by 1-week washout period and crossover to another 1-week of challenge or placebo dose. Symptoms were recorded prior to commencing the study and at the end of each week's challenge.

A previously published Likert scale symptom questionnaire in electronic format (www.surveymonkey.com) was used to monitor the symptoms during the study. This questionnaire was completed four times during the study. The first questionnaire was completed at baseline prior to commencing the study and a further three times by the parents during the food challenge: after completion of 'week -1' (prior to commencing the washout period); prior to commencing 'week -2' of the challenge; and at completion of the study. The parents received instructions on how to monitor their child's symptoms during the study at the first assessment visit. Symptoms in the questionnaire were ranked from 1 to 5 indicating what the child was feeling compared to the prior week after consuming the challenge biscuit on week 1 and 3.

Parents were required to contact the researcher if a reaction occurred during the study and questionnaires were reviewed by the researcher during the study to ensure accurate/correct recording of symptoms and to ensure that symptoms were not related to concomitant illness.

Intervention Type
Other

Primary outcome(s)

Allergy symptoms measured using a previously published Likert scale symptom questionnaire in electronic format at baseline prior to commencing the study, after completion of “week 1” (prior to commencing the washout period), prior to commencing “week 2” of the challenge; and at completion of the study.

Key secondary outcome(s))
Allergic reaction reported by parents at any time during the study

Completion date
13/03/2015

Eligibility

Key inclusion criteria
1. Children between 8 months and 5 years of age
2. Confirmed (through protocolised home re-introduction) non-IgE mediated gastrointestinal soya allergy
3. Wheat and corn syrup tolerant, as the challenge food contained both these ingredients
4. Stable in symptoms following the elimination diet and well managed from a dietary and medical perspective (no medication changes during the study)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
8 months

Upper age limit
5 years

Sex
All

Total final enrolment
22

Key exclusion criteria
1. Patients who had commenced a new medication within 2 weeks of starting the study
2. Soya induced Food Protein Induced Enterocolitis Syndrome
3. As endoscopies are not routinely performed, this study did not distinguish between children that had eosinophilic oesophagitis, food protein-induced enteropathy and other non-IgE medidated food allergic conditions

Date of first enrolment

01/09/2014

Date of final enrolment
20/02/2015

Locations

Countries of recruitment
United Kingdom

United States of America

Study participating centre
Great Ormond Street Hospital
Great Ormond Street
Holborn
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Sponsor information

Organisation
Great Ormond Street Hospital

ROR
https://ror.org/00zn2c847

Funder(s)

Funder type
Industry

Funder Name
DuPont Nutrition & Health (Solae, LLC), St. Louis, MO), USA

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Rosan Meyer (r.meyer@imperial.ac.uk).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2020	18/03/2020	Yes	No