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Do people who have anaphylactic reactions to insect stings or foods have specific forms of genes for hormones involved in controlling blood pressure?

Submission date
26/01/2019

Recruitment status
No longer recruiting

Registration date
13/02/2019

Overall study status
Completed

Last Edited
15/02/2019

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
Shock is when there is not enough blood flow to the tissues of the body. When a person has anaphylaxis (a serious allergic reaction), high levels of a chemical called histamine are released. Histamine causes blood vessels to dilate (open up). This causes blood pressure to drop and can lead to anaphylactic shock. It has previously been shown that the severity of anaphylactic shock in people who are allergic to bee or wasp stings is linked to low levels of hormones in the blood that control blood pressure. However, there is currently no evidence of whether this is also true in people with food allergies. This research team has already done some analysis of the genes for these hormones in people with food allergies. This study aims to compare the genes for blood pressure hormones in people with no allergies, people with allergies to airborne allergens (for example, pollen) but not food, people with allergies to bee or wasp stings who have had anaphylactic reactions, people with food allergies who have never had an anaphylactic reaction and people with food allergies who have anaphylactic reactions.

Who can participate?
People with no allergies, people with allergies to airborne allergens (for example, pollen) but not food, people with allergies to bee or wasp stings who have had anaphylactic reactions, people with food allergies who have never had an anaphylactic reaction and people with food allergies who have anaphylactic reactions. Participants must not be taking some medicines that affect blood pressure.

What does the study involve?
The participants will have a sample of blood taken in the morning before they eat. The blood will be used to prepare a sample of DNA, which will be analysed to show which forms of the blood pressure-controlling genes the person has. The details of their allergies and anaphylactic reactions will be taken from their medical records.

What are the possible benefits and risks of participating?
There is no direct benefit to the participants. The potential risks relate to discomfort from the blood-taking.

Where is the study run from?
St Helier Hospital, Carshalton (UK)

When is the study starting and how long is it expected to run for?
April 1997 to January 2012

Who is funding the study?
Epsom and St Helier Hospitals NHS Trust (UK)

Who is the main contact?
Dr Veronica Varney, veronica.varney@btinternet.com

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
vv14/97

Study information

Scientific Title
Hymenoptera venom anaphylaxis and food allergy induced anaphylaxis: A study of the renin and angiotensin system

Study objectives
In 1993, Hermann and Ring demonstrated that the severity of anaphylactic shock following bee or wasp stings was linked to low levels of renin and angiotensin 1 and II in the blood permitting hypotension. To date, no published studies have examined this in subjects with food-induced anaphylaxis. Our preliminary data from this study collected in 1998 has shown that 85% of subjects with anaphylaxis to food had low levels of serum ACE and were homozygous (II genotype) or heterozygous (ID genotype) for the angiotensin gene deletion. This deletion results in low activity of angiotensin converting enzymes and reduced angiotensin II production compared with homozygous gene state (DD) that is associated with high levels of production.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 04/04/1997.
2. Re-approved 05/08/2005, London-Surrey borders Ethics Committee (Usual meeting venue Health Research Authority, Skipton House, 80 London Road, London, SE1 6LH; +44 (0)20 7972 2568; NRESCommittee.London-SurreyBorders@nhs.net), ref: 14/97

Study design
Observational cross-sectional study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Anaphylactic shock

Interventions
The study will be based on patients normally referred to the Allergy Clinic at St Helier Hospital. From their outpatient attendance and assessment, suitable patients will be selected and asked to make a single attendance before breakfast on a single occasion. Five groups of patients will

be selected (non-atopic, airborne allergy only, food allergies, food allergy with anaphylaxis, bee and wasp allergy).

In each patient a single visit on a Saturday morning before breakfast is required. The patient must lie horizontal for 20 minutes. After this time blood will be taken at 4°C and spun immediately in a refrigerated centrifuge and stored. The patient may then eat and drink and apart from details of the anaphylaxis and timing and results of skin tests no further visits are required. Most of the information can be collected onto a short questionnaire directly from the notes. The patients will be selected following their assessment in the allergy clinic

Intervention Type
Other

Primary outcome measure
1. Serum ACE level
2. Plasma renin level
3. Plasma angiotensin-1 level
4. Polymorphisms of genes related to the renin angiotensin system including ACE, renin, angiotensinogen (AGT235), chymase CMI-1903, AT-2 receptor

Secondary outcome measures
N/A

Overall study start date
04/04/1997

Completion date
01/01/2012

Eligibility

Key inclusion criteria
Anaphylaxis patients:
1. Wasp- and bee-induced anaphylaxis (>50) or food-induced allergy with anaphylaxis (>50)

Control participants:
2. Food allergy without anaphylaxis (>30) or atopic without food allergies (>30) or non-atopic control (>100)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants

Wasp and bee induced anaphylaxis (>50), food induced allergy without anaphylaxis (>50), food allergy without anaphylaxis (>30), atopic without food allergies (>30), non-atopic control (>100)

Key exclusion criteria
1. Pregnant
2. Taking drugs that would affect the renin-angiotensin system and levels of blood hormones
3. Involved in any other studies which would be either disadvantageous to the participant's health or the benefit of the study

Date of first enrolment
05/04/1997

Date of final enrolment
06/08/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St Helier Hospital
Wrythe Lane
Carshalton
United Kingdom
SM5 1AA

Sponsor information

Organisation
R&D department at St Helier Hospital

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/019hb9542

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Epsom and St Helier Hospitals NHS Trust

Results and Publications

Publication and dissemination plan
Results were published in 2012. A further paper (Bi-allelic and tri-allelic gene combinations of ACE, Angiotensinogen and Chymase and their association with IgE mediated systemic anaphylaxis) is ready for submission.

Intention to publish date
01/03/2019

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	19/12/2012	28/01/2019	Yes	No
Participant information sheet			15/02/2019	No	Yes