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A study to validate a method of measurement of dermal blood flow in healthy human volunteers after topical application of allyl isothiocyanate (AITC)

Submission date
25/09/2018

Recruitment status
No longer recruiting

Registration date
08/10/2018

Overall study status
Completed

Last Edited
07/01/2022

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Allyl Isothiocyanate (AITC) is a compound found in common foods such as mustard and horseradish. It can be dissolved in oil and applied to the skin to activate sensory nerves to produce visible, measurable reactions (such as mild irritation or redness). These reactions are due in part to an increase in blood flow to the areas of AITC application on the skin. The increase in blood flow can be measured using a method called laser speckle contrast imaging. This study aims to develop a method to reliably measure the reactions caused by AITC applied to the skin using laser speckle contrast imaging. If successful, this method can be used in future clinical trials to test the ability of new drugs to reduce these reactions.

Who can participate?
Healthy volunteers of any gender aged 18-65

What does the study involve?
All participants have small volumes of AITC dissolved in mineral oil applied to their forearms during two visits, with a 2-week break between visits. The resulting reactions are examined using laser speckle contrast imaging about 1 week after each visit.

What are the possible benefits and risks of participating?
There is no clinical benefit to this trial. Possible side effects are easily treated and include mild skin redness, blistering, pain, or itching. Pain and itching are not expected to last longer than a few hours, but redness and blistering may take several weeks to subside.

Where is the study run from?
Quotient Clinical, Ltd (UK)

When is the study starting and how long is it expected to run for?
September 2017 to November 2018

Who is funding the study?
Genentech, Inc. (USA)

Who is the main contact?
global-roche-genentech-trials@gene.com, reference study ID GE40309

Contact information

Type(s)
Public

Contact name
Dr Clinical Trials

Contact details
1 DNA Way
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United States of America
94080

Additional identifiers

EudraCT/CTIS number
2017-003498-33

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
GE40309

Study information

Scientific Title
Exploratory skin challenge study using laser speckle contrast imaging to develop and assess the reproducibility of a method for assessing changes in forearm skin blood flow in healthy human volunteers before and after topical application of allyl isothiocyanate

Study objectives
This study aims to demonstrate the safety and reproducibility of a topical challenge method to be used in Phase I clinical trials.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Health and Social Care Research Ethics Committee A, 03/10/2017, Board Number: 17/NI/0183

Study design
Interventional single-center open-label single-group assignment

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Other

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

Health condition(s) or problem(s) studied
Topical application of allyl isothiocyanate

Interventions
Allyl Isothiocyanate (AITC) diluted in mineral oil: Participants will receive a small volume of 10% and 15% AITC (25 microliters), to be applied to localized forearm regions defined by small O-rings placed on the skin. AITC will be applied during two visits, with an approximately 2-week washout period between visits. Follow-up will occur approximately 1 week after each visit.The resulting reactions will be examined using laser speckle contrast imaging.

Intervention Type
Other

Primary outcome measure
Reproducibility across two visits in the change in dermal blood flow after AITC challenge, measured by Laser Speckle Contrast Imaging at visits 1 and 2

Secondary outcome measures
1. Percentage of participants with adverse events (AEs), measured from baseline through to the end of the study (up to 24 days)
2. Pain and itch score, measured by interviewer-administered questionnaire at baseline and visits 1 and 2

Overall study start date
01/09/2017

Completion date
30/11/2018

Eligibility

Key inclusion criteria
1. Participants must be willing and able to communicate and participate in the whole study
2. Able to sit or lay down for up to 2 hours

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
30

Total final enrolment
23

Key exclusion criteria
1. Participants who have received any investigational medicinal product (IMP) in a clinical research study within at least 3 months of the first date of skin challenge (Visit 1)
2. Participants who are study site employees, or immediate family members of a study site or sponsor employee
3. Participants who have previously been enrolled in this study
4. History of any drug or alcohol abuse in the past 2 years
5. Regular alcohol consumption in males greater than (>) 21 units per week and females >14 units per week
6. Current smokers and those who have smoked within the last 12 months. A breath carbon monoxide reading of greater than 10 parts per million (ppm)
7. Positive drugs of abuse test result
8. History of clinically significant cardiovascular, renal, hepatic, chronic respiratory or gastrointestinal disease, or psychiatric disorder, as judged by the investigator
9. History of serious adverse reaction or serious hypersensitivity to the challenge agent (AITC), vehicle (mineral oil), or procedures
10. History of dermatographism
11. Presence of active allergy requiring treatment, as judged by the investigator
12. Presence or history of clinically significant skin disorders, as judged by the investigator
13. History of trauma or surgery to the arm but not including wrist or hand injury/surgery
14. Excessive forearm hair growth, tattoos or other physical or behavioural characteristics that may interfere with the study, as judged by the investigator
15. Participants who are taking, or have taken, any prescribed or over-the-counter drug (other than 4 grams [g] per day paracetamol, hormone replacement therapy and hormonal contraception) in the 7 days before non-investigational medicinal product (AITC) administration
16. Failure to satisfy the investigator of fitness to participate for any other reason

Date of first enrolment
20/10/2017

Date of final enrolment
22/03/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Quotient Clinical Ltd, Clinical Research Unit
Mere Way
Nottingham
United Kingdom
NG11 6JS

Sponsor information

Organisation
Genentech, Inc

Sponsor details
1 DNA Way
South San Francisco
United States of America
94080

Sponsor type
Industry

Website
www.roche.com/about_roche/roche_worldwide.htm

ROR
https://ror.org/011qkaj49

Funder(s)

Funder type
Industry

Funder Name
Genentech

Alternative Name(s)
Genentech, Inc., Genentech USA, Inc., Genentech USA

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Publication and dissemination plan
Publication is planned in a peer-reviewed journal. There is no current plan to make additional study documents available.

Intention to publish date
20/11/2019

Individual participant data (IPD) sharing plan
Participant-level data will not be available because it is confidential, proprietary information. Study data will be held at Genentech, Inc.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		02/06/2020	07/01/2022	Yes	No
HRA research summary			28/06/2023	No	No