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Role of TLR2 in the Sensing of oxidants and ensuing Inflammation

Submission date
25/10/2012

Recruitment status
No longer recruiting

Registration date
26/02/2013

Overall study status
Completed

Last Edited
19/12/2017

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Most cells in your body can detect the presence of something that can cause a disease (a pathogen) like a virus or bacteria, or an environmental factor like pollution. If your cells detect a pollutant like cigarette smoke, they react by removing it from your body in the same way as viruses and bacteria. We believe that susceptibility to infection may be influenced by environmental pollutants like cigarette smoke. We would like to see if this is the case, and if so why this happens.

Who can participate?
Healthy volunteers (smokers and non-smokers).

What does the study involve?
We need blood samples from healthy smokers (within 20 minutes of smoking a cigarette) and non-smokers so that we can look at their response to bacteria and viruses and the effect that smoking has on these responses. These tests will be carried out a laboratory at Imperial College. We would like to take a small sample of your blood - about 10 tablespoons. This will be taken using a needle from a vein in your arm by a trained research nurse or qualified doctor in the Unit of Critical Care Medicine at the Royal Brompton Hospital, and should only take about 20 minutes. You will need to inform us of any medication that you are taking. At the end of the study we will reimburse all your travelling expenses.

What are the possible benefits and risks of participating?
There is a slight risk of a small bruise where the needle is put in, and occasionally people feel faint when blood is taken, but there are no other risks involved. We will only carry out those tests detailed above on your blood sample. We will not carry out any tests for serious infections such as HIV and there is no need to declare such tests on an insurance or mortgage application. In the very unlikely event of your coming to any harm, Imperial College has insurance in place so that you may receive compensation without having to prove negligence on our part. The blood samples you give will be coded before any tests are performed on them, so that you cannot be identified from the samples. All of your details will be kept strictly confidential. Some blood may be stored for future use in research in this area.

Where is the study run from?
Royal Brompton & Harefield NHS Foundation Trust (UK).

When is the study starting and how long is it expected to run for?
August 2008 to August 2013.

Who is funding the study?
Wellcome Trust (UK).

Who is the main contact?
Dr Mark Paul-Clark
m.paul-clark@imperial.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Mark Paul-Clark

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
5843

Study information

Scientific Title
Role of TLR2 in the Sensing of oxidants and ensuing Inflammation: Implications for therapeutic Intervention - an observational study

Acronym
TSI

Study objectives
The aim of this project is to study how oxidants are sensed by Toll like receptors (TLRs)

1. Determine the effects that oxidants have on the ectodomain of TLR2
2. Assess the requirements for the TLR adaptor proteins MyD88 and TIRAP in oxidants dependant signalling
3. To assess the involvement of other PRRs in oxidant induced inflammation
4. Assess the differences in gene activation between classical TLR2 ligands and oxidants
5. Grow out blood-derived stem cells for assessment

More details can be found at: http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=5843

Ethics approval required
Old ethics approval format

Ethics approval(s)
Royal Brompton & Harefield NHS Trust Ethics Committee, 08/H0708/69

Study design
Observational study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Immunology and inflammation

Interventions
Blood will be taken from volunteers who are either healthy smokers (within 20 mins of smoking a cigarette) or non-smokers. The blood will either be directly plated out into 96 well plates or cells isolated or grown out and characterised for their responses to various agonists and a number of mediators and cytokines will be measured. The total time a volunteer is need for is 20 mins although they may be asked back to participate again.

Intervention Type
Other

Phase

Not Applicable

Primary outcome measure
The blood or cellular responses will be compared between smokers and non-smokers. To assess the differences that oxidative exposure will have on smokers just 20 mins after having a cigarette.

Secondary outcome measures
No secondary outcome measures

Overall study start date
06/08/2008

Completion date
08/08/2013

Eligibility

Key inclusion criteria
Healthy volunteer (either a smoker or non-smoker)

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 100

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
06/08/2008

Date of final enrolment
08/08/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Brompton & Harefield NHS Foundation Trust
London
United Kingdom
SW3 6NP

Sponsor information

Organisation
Wellcome Trust (UK)

Sponsor details
Queen Square
London
United Kingdom
WC1N 3BG

Sponsor type
Charity

ROR
https://ror.org/029chgv08

Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust (UK) ref: WT083429MA

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration