ISRCTN13109642 https://doi.org/10.1186/ISRCTN13109642

Protocol for the donation of samples by volunteers for laboratory research

Submission date	Recruitment status	[ ] Prospectively registered
02/02/2023	Recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
03/02/2023	Ongoing	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
18/04/2024	Other	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
This study aims to obtain blood and/or urine, stool, skin, sputum, saliva, mucosal or nasal samples from healthy volunteers and patient volunteers for laboratory research, relating to the causes and treatment of disease, in order to identify markers of disease and drug effect or development of new laboratory methods.

Who can participate?
Men and women 18 years old or over

What does the study involve?
This study will involve ad hoc visits to the Medicines Evaluation Unit. After written informed consent is obtained, participants will be assessed for their eligibility to donate the samples required according to the specific procedure to be undertaken. Participants have one or more of the following samples taken at a single visit: sputum, blood, urine, nasal, stool or skin.

What are the possible benefits and risks of participating?
All sampling procedures are considered safe. There is a small risk of side effects such as bruising, bleeding and infection. This is laboratory research so there is no direct benefit to the participant.

Where is the study run from?
Medicines Evaluation Unit (UK)

When is the study starting and how long is it expected to run for?
November 2009 to December 2030

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Clinical Research Leader

Contact information

Type(s)
Public

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Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
149078

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
DS-10-01, IRAS 149078, 46616

Study information

Scientific Title
Protocol for the donation of blood, urine, stool, dermatological, sputum and nasal samples by healthy volunteers and patient volunteers for laboratory research

Study objectives
Identifying markers of disease and developing new assays

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/04/2010, North West Preston Research Ethics Committee (HRA Centre Manchester, Barlow House, 3rd Floor, 4 Minshull Street, Manchester M1 3DZ, UK; +44 (0) 2071048290; preston.rec@hra.nhs.uk), ref: 10/H1016/25

Study design
Observational cross sectional study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Pharmaceutical testing facility

Study type(s)
Diagnostic

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

Health condition(s) or problem(s) studied
Healthy volunteers and patient volunteers of all conditions

Interventions
Participants have one or more of the following samples taken at a single visit: sputum, blood, urine, nasal, stool or skin.

Intervention Type
Other

Primary outcome measure
Sputum eosinophil counts in stable state measured using cytology at a single timepoint

Secondary outcome measures
Sputum supernatant cytokines including IL-8 and TNF-α in stable state measured using immunoassay at a single timepoint

Overall study start date
01/11/2009

Completion date
31/12/2030

Eligibility

Key inclusion criteria
1. Able to give written informed consent
2. Males and females aged over 18 years
3. Procedure specific criteria

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
At least 2000

Key exclusion criteria
1. History of anaemia or identified by haemocue test at screening or other clinically significant haematological disorders for blood donation
2. Current acute illness
3. Pregnancy or breastfeeding
4. History of Hepatitis B/C or HIV infection or a positive test at screen if required by the specific project

5. Volunteers who have donated to the blood transfusion service in the past 4 months, if applicable (applicable for blood donation or if specified for other procedures as per project-specific exclusion criteria)
6. Suspected use of drugs of abuse or positive drug screen, if required
7. Any contraindications for nasal sampling e.g. history of epistaxis, nasal defects, as assessed by the physician
8. Procedure-specific criteria and contraindications for performing the specific procedure
9. Any reason that the physician deems the subject not suitable to undertake the procedure(s)

Date of first enrolment
07/05/2010

Date of final enrolment
31/12/2029

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Medicines Evaluation Unit Limited
The Langley Building
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Sponsor information

Organisation
Medicines Evaluation Unit

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Sponsor type
Research organisation

Website
http://www.meu.org.uk/

ROR
https://ror.org/05e497m36

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publications in high-impact peer-reviewed journals, the first one in 2025.

Intention to publish date
01/01/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to the exploratory nature of the research and assays.

IPD sharing plan summary
Not expected to be made available