

Protocol for the donation of samples by volunteers for laboratory research

Submission date 02/02/2023	Recruitment status Recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 03/02/2023	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 18/04/2024	Condition category Other	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

149078

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Diagnostic

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

United Kingdom

England

Study participating centre

Medicines Evaluation Unit Limited

The Langley Building

Southmoor Road

Wythenshawe

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Sponsor information

Organisation

Medicines Evaluation Unit

ROR

<https://ror.org/05e497m36>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

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