

# Response to routine immunisations in human immunodeficiency virus (HIV) infected adults

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| <b>Submission date</b><br>22/01/2011   | <b>Recruitment status</b><br>No longer recruiting        | <input type="checkbox"/> Prospectively registered    |
|  |  | <input type="checkbox"/> Protocol                    |
| <b>Registration date</b><br>10/03/2011 | <b>Overall study status</b><br>Completed                 | <input type="checkbox"/> Statistical analysis plan   |
|  |  | <input type="checkbox"/> Results                     |
| <b>Last Edited</b><br>18/11/2016       | <b>Condition category</b><br>Infections and Infestations | <input type="checkbox"/> Individual participant data |
|  |  | <input type="checkbox"/> Record updated in last year |

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
RG\_09-034

# Study information

## Scientific Title

Response to routine immunisations in human immunodeficiency virus (HIV) infected adults: a cross-sectional cohort study

## Acronym

AIR Study

## Study objectives

The aim of this study is to investigate the level and duration of response to routine vaccinations in human immunodeficiency virus (HIV) infected adults compared with uninfected adults and how this relates to the function of the immune system in these individuals.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

National Research Ethics Committee - North Staffordshire Research Ethics Committee, 10/07/2009, ref: 09/H1204/53

## Study design

Cross-sectional cohort study

## Primary study design

Observational

## Secondary study design

Cross-section survey

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please contact [c.maclennan@bham.ac.uk](mailto:c.maclennan@bham.ac.uk) to request a patient information sheet

## Health condition(s) or problem(s) studied

Human immunodeficiency virus (HIV) infection

## Interventions

Nationally-recommended immunisation against vaccine-preventable diseases for HIV-infected adults.

## Cases:

At recruitment Pneumococcal, Men C, Hib, HepB, HepA and TetDipIPV vaccinations, depending on previous vaccination history and psychosocial factors questionnaire. Annual influenza

vaccination. Vaccination response assessed by antibody titres. Booster vaccinations offered in case of sub-optimal response.

Controls:

As for cases, but no psychosocial factors questionnaire.

Duration of treatment and follow up (both arms): five years.

### **Intervention Type**

Other

### **Phase**

Not Applicable

### **Primary outcome measure**

Proportion of HIV-infected patients producing a response to Haemophilus influenzae type b conjugate vaccination of 1.0 ug per ml anti-polyribosyl phosphate antibodies (considered protective levels) at 1 month post-vaccination compared with HIV-uninfected control subjects.

Acute vaccination responses measured at baseline and one month post-vaccination with clinical laboratory serological assays for antibody titres.

### **Secondary outcome measures**

1. Level of immune response to each vaccination at 1 month post-vaccination in study participants compared with control group and correlation of immune response to degree of immune suppression of each participant gauged by CD4 count
2. Duration of immune response to each vaccination through course of study
3. Correlation of immune response to psychosocial factors
4. Occurrence of any vaccine-preventable diseases during the course of the study

Acute vaccination responses measured at baseline and one month post-vaccination with clinical laboratory serological assays for antibody titres. Duration of immune response measured at four-monthly clinic visits (cases) and annual appointments (controls) over 5 year duration of study. Psychosocial factors measured at baseline and four months via a patient questionnaire. Vaccine-preventable disease occurrence measured through continuous follow in outpatient clinic over 5 year duration of study.

### **Overall study start date**

24/09/2009

### **Completion date**

24/09/2014

## **Eligibility**

### **Key inclusion criteria**

1. Aged over 18 years old, either sex
2. Informed consent given
3. Participant cases: proven HIV infection
4. Participant controls: proven absence of HIV-infection

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

Participant cases: 1000; participant controls: 115

**Key exclusion criteria**

1. Under 18 years of age
2. Informed consent withheld
3. HIV-status unknown

**Date of first enrolment**

24/09/2009

**Date of final enrolment**

24/09/2014

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**

**MRC Centre for Immune Regulation**

Birmingham

United Kingdom

B15 2TT

**Sponsor information****Organisation**

University of Birmingham (UK)

**Sponsor details**

Research and Commercial Services  
Edgbaston  
Birmingham  
England  
United Kingdom  
B15 2TT

**Sponsor type**

University/education

**Website**

<http://www.birmingham.ac.uk/index.aspx>

**ROR**

<https://ror.org/03angcq70>

## **Funder(s)**

**Funder type**

University/education

**Funder Name**

University of Birmingham (UK) - Clinical Immunology Service and University Hospital Birmingham  
Adult HIV Service

## **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