

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

Submission date 22/01/2011	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 10/03/2011	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 18/11/2016	Condition category Infections and Infestations	☐ Individual participant data
		☐ 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

Protocol serial number
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

Primary study design

Observational

Study design

Cross-sectional cohort study

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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

United Kingdom

England

Study participating centre

MRC Centre for Immune Regulation

Birmingham

United Kingdom

B15 2TT

Sponsor information

Organisation

University of Birmingham (UK)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration