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

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