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Study of measles immunisation

Submission date	Recruitment status	[_] Prospectively registered
25/06/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
25/06/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
21/03/2013	Infections and Infestations	

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
NCT00247091

Secondary identifying numbers
059114

Study information

Scientific Title
Impact of human immunodeficiency virus on measles and measles immunisation: an observational cohort study

Study objectives
We conducted an observational study to assess the immunogenicity of standard-titre measles vaccine in Human Immunodeficiency Virus (HIV)-infected and uninfected Zambian children. The study hypothesis was that HIV-infected children would have higher rates of primary and secondary measles vaccine failure compared to uninfected children, contributing to decreased levels of population immunity to measles and facilitating measles virus transmission in regions of high HIV prevalence.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Johns Hopkins University Ethics Committee on Human Research, London School of Hygiene and Tropical Medicine (UK)
2. University of Zambia Research Ethics Committee (Zambia)

Study design
Observational, natural history, longitudinal, defined population, prospective study

Primary study design
Observational

Secondary study design
Cross-section survey

Study setting(s)
Other

Study type(s)
Screening

Participant information sheet

Health condition(s) or problem(s) studied
HIV infection, measles, children

Interventions
We conducted a longitudinal study to compare the primary vaccine failure rate and rate of antibody decline following administration of standard-titre measles vaccine at nine months of age to HIV-infected and HIV-uninfected Zambian children. The Edmonston-Zagreb measles vaccine strain was administered subcutaneously in the upper arm by a trained health worker. At the time of vaccination, and at each follow-up visit, a study clinical officer or nurse interviewed the mother or guardian about the childs medical history, examined the child for signs of illness, and recorded data on immunisations received as well as the child's length and weight on standard case-report forms. We randomly assigned children to follow-up at one or three months post-vaccination, and asked mothers of all children to return at 15 and 27 months post-vaccination and to seek care from the study team any time the child was ill. Venous blood

samples were obtained on the day of vaccination and at one or three, and 15 and 27 months post-vaccination. Antibodies to HIV-1 were measured again by Enzyme Immunoassay (EIA) and antibody-positive samples were assayed for HIV-1 RNA by reverse transcriptase polymerase chain reaction. A modified plaque reduction neutralisation assay was used to measure measles antibodies. Plasma samples were tested in parallel with the Second International World Health Organisation (WHO) Serum Standard, 66/202. Logarithms of antibody levels were calculated, and geometric mean measles antibody concentrations and their 95% Confidence Intervals (CI) estimated.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Standard-titre measles vaccine

Primary outcome measure
Primary neutralising antibody responses and persistence of neutralising antibodies following measles vaccination of HIV-1-infected and uninfected children.

Secondary outcome measures
Seroconversion after measles vaccination of HIV-1-infected and uninfected children.

Overall study start date
05/01/2000

Completion date
09/01/2004

Eligibility

Key inclusion criteria
1. Children aged two to eight months (either sex) presenting for well-child care
2. Reside within 10 miles of the study clinic
3. Parents or caretakers provide signed informed consent

Participant type(s)
Patient

Age group
Child

Lower age limit
2 Months

Upper age limit
8 Months

Sex
Both

Target number of participants
700

Key exclusion criteria
Children with severe illness.

Date of first enrolment
05/01/2000

Date of final enrolment
09/01/2004

Locations

Countries of recruitment
United States of America

Zambia

Study participating centre
Johns Hopkins University Bloomberg School of Public Health
Baltimore, Maryland
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21205

Sponsor information

Organisation
Johns Hopkins University Bloomberg School of Public Health (USA)

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Sponsor type
University/education

Website
http://www.jhsph.edu/

ROR
https://ror.org/00za53h95

Funder(s)

Funder type
Charity

Funder Name
The Wellcome Trust (UK) (grant ref: 059114)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results:	01/08/2007		Yes	No