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# Study of measles immunisation

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

**ClinicalTrials.gov (NCT)**
NCT00247091

**Protocol serial number**
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

## Study type(s)
Screening

## 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(s)
Primary neutralising antibody responses and persistence of neutralising antibodies following measles vaccination of HIV-1-infected and uninfected children.

### Key secondary outcome(s))
Seroconversion after measles vaccination of HIV-1-infected and uninfected children.

### 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

### Healthy volunteers allowed
No

### Age group
Child

### Lower age limit
2 months

### Upper age limit
8 months

### Sex
All

### 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
United States of America
21205

# Sponsor information

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

### ROR
https://ror.org/00za53h95

# Funder(s)

### Funder type
Charity

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

# Results and Publications

### 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: | | | | |

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| Results article | 01/08/2007 | Yes | No |