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A phase I study of NYVAC C in healthy volunteers at low risk of human immunodeficiency virus (HIV) infection

Submission date	Recruitment status	[_] Prospectively registered
07/09/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/09/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
18/01/2011	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

Protocol serial number
EV01

Study information

Scientific Title

Acronym

EuroVac01

Study objectives
To explore the safety and immunogenicity of two injections of NYVAC HIV-C in healthy male and female volunteers at low risk of HIV infection.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)

Health condition(s) or problem(s) studied
Human immunodeficiency virus (HIV)

Interventions
NYVAC-HIV C (vP2010) or placebo.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
The safety and immunogenicity of NYVAC C, and the respective end-points are:
1. Safety: grade 3 or above local general adverse events
2. Immunogenicity: cellular responses assessed using the ELISPOT technique

Key secondary outcome(s)
1. All grade 1 and 2 adverse events within 28 days of a vaccination
2. Antibody responses
3. Cellular responses

Completion date
07/10/2004

Eligibility

Key inclusion criteria
1. Male or female
2. Age between 18 and 55 years on the day of screening

3. Available for follow-up for the duration of the study (52 weeks from screening)
4. Able to give written informed consent
5. At low risk of HIV and willing to remain so for the duration of the study
6. Willing to undergo a HIV test
7. Willing to undergo a genital infection screen
8. If heterosexually active female, using an effective method of contraception with partner (combined oral contraceptive pill; injectable contraceptive; intra-uterine contraceptive device [IUCD]; consistent record with condoms if using these; physiological or anatomical sterility in self or partner) from 14 days prior to the first vaccination until 4 months after the last, and willing to undergo urine pregnancy tests prior to each vaccination
9. If heterosexually active male, using an effective method of contraception with their partner from the first day of vaccination until 4 months after the last vaccination

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Pregnant or lactating
2. Clinically relevant abnormality on history or examination including history of grand-mal epilepsy, severe eczema, immunodeficiency or use of immunosuppressives in preceding 3 months
3. Receipt of live attenuated vaccine within 60 days or other vaccine within 14 days of enrolment
4. Receipt of blood products or immunoglobin within 4 months of screening
5. Participation in another trial of a medicinal product, completed less than 30 days prior to enrolment
6. History of severe local or general reaction to vaccination
7. HIV 1/2 positive or indeterminate on screening
8. Positive for hepatitis B surface antigen, hepatitis C antibody or serology indicating active syphilis requiring treatment
9. Grade 1 routine laboratory parameters
10. Unlikely to comply with protocol

Date of first enrolment
04/08/2003

Date of final enrolment
07/10/2004

Locations

Countries of recruitment
United Kingdom

England

Switzerland

Study participating centre
MRC Clinical Trials Unit
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
Imperial College London (UK)

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Government

Funder Name
European Commission (5th Framework programme) (Belgium)

Alternative Name(s)
European Union, Comisión Europea, Europäische Kommission, EU-Kommissionen, Euroopa Komisjoni, EC, EU

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	13/06/2008		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes