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

Submission date	<b>Recruitment status</b> No longer recruiting	<ul><li>Prospectively registered</li></ul>		
07/09/2005		☐ Protocol		
Registration date 21/09/2005	Overall study status Completed	Statistical analysis plan		
		[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

#### Contact name

Dr Sheena McCormack

#### Contact details

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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

## Study design

Randomised controlled trial

#### Primary study design

Interventional

#### 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