

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

<b>Submission date</b> 07/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 21/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 18/01/2011	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Study website

<http://www.ctu.mrc.ac.uk/studies/eurovac1.asp>

## Contact information

### Type(s)

Scientific

### Contact name

Dr Sheena McCormack

### Contact details

MRC Clinical Trials Unit  
222 Euston Road  
London  
United Kingdom  
NW1 2DA

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

### Secondary study design

Randomised controlled trial

### Study setting(s)

Not specified

### Study type(s)

Not Specified

### Participant information sheet

### 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 measure

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

### **Secondary outcome measures**

1. All grade 1 and 2 adverse events within 28 days of a vaccination
2. Antibody responses
3. Cellular responses

### **Overall study start date**

04/08/2003

### **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

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Sex**

Both

### **Target number of participants**

24

### **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 immunoglobulin 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**

England

Switzerland

United Kingdom

**Study participating centre**

**MRC Clinical Trials Unit**

London

United Kingdom

NW1 2DA

## Sponsor information

**Organisation**

Imperial College London (UK)

**Sponsor details**

Research Services

Faculty Building

Exhibition Road

London  
England  
United Kingdom  
SW7 2AZ

**Sponsor type**

University/education

**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, Ευρωπαϊκή Επιτροπή, Европейская комиссия, Evropské komise, Commission européenne, Choimisiúin Eorpaigh, Europskoj komisiji, Commissione europea, La Commissione europea, Eiropas Komisiju, Europos Komisijos, Európai Bizottságrol, Europese Commissie, Komisja Europejska, Comissão Europeia, Comisia Europeană, Európskej komisii, Evropski komisiji, Euroopan komission, Europeiska kommissionen, EC, EU

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

## **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?
<a href="#">Results article</a>	results	13/06/2008		Yes	No