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

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

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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 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
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, Ευρωπαϊκής Επιτροπής, Европейската комисия, Evropské komise, Commission européenne, Choimisiúin Eorpaigh, Europskoj komisiji, Commissione europea, La Commissione europea, Eiropas Komisiju, Europos Komisijos, Európai Bizottságról, 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?
Results article	results	13/06/2008		Yes	No