A phase I trial to assess the safety of 4 ml DNA C (intramuscular [IM]), and the safety and immunogenicity of DNA C followed by NYVAC C (IM) in an open, randomised comparison to NYVAC C alone in healthy volunteers at low risk of human immunodeficiency virus (HIV) infection

Submission date	Recruitment status No longer recruiting	Prospectively registered	
06/09/2005		☐ Protocol	
Registration date 21/09/2005	Overall study status Completed Condition category	Statistical analysis plan	
		[X] Results	
Last Edited		☐ Individual participant data	
18/01/2011	Infections and Infestations		

Plain English summary of protocol

Not provided at time of registration

Study website

http://www.ctu.mrc.ac.uk/studies/eurovac2.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

EV02

Study information

Scientific Title

Acronym

EuroVac 02

Study objectives

The primary objectives are to explore the safety of the DNA C construct and the prime-boost regimen, and to compare the immunogenicity of the prime boost regimen to the single agent NYVAC C in healthy 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

DNA HIV-C & NYVAC HIV-C (vP2010) vaccines versus NYVAC HIV-C alone.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

- 1. Safety: local & general adverse events within 7 and 28 days
- 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

21/02/2005

Completion date

24/07/2006

Eligibility

Key inclusion criteria

- 1. Age between 18 and 55 years on the day of screening
- 2. Available for follow-up for the duration of the study (54 weeks from screening)
- 3. Able to give written informed consent
- 4. At low risk of HIV and willing to remain so for the duration of the study
- 5. Willing to undergo a HIV test
- 6. Willing to undergo a genital infection screen
- 7. 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
- 8. 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

40

Key exclusion criteria

- 1. Pregnant or lactating
- 2. Clinically relevant abnormality on history or examination including history of grand-mal epilepsy, severe eczema, allergy to eggs, 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. Positive for DNA/ANA antibodies at titre considered clinically relevant by immunology laboratory
- 10. Grade 1 routine laboratory parameters
- 11. Unlikely to comply with protocol

Date of first enrolment

21/02/2005

Date of final enrolment

24/07/2006

Locations

Countries of recruitment

England

Switzerland

United Kingdom

Study participating centre MRC Clinical Trials Unit London United Kingdom

NW1 2DA

Sponsor information

EuroVacc Foundation (Switzerland)

Sponsor details

6, Rue de la Grotte Lausanne Switzerland 1003

Sponsor type

Research organisation

Website

http://www.eurovacc.org

ROR

https://ror.org/04f2nz275

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, Εвροπεйската 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