# 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	<b>Recruitment status</b> No longer recruiting	<ul><li>Prospectively registered</li></ul>		
06/09/2005		☐ 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

#### Contact name

Dr Sheena McCormack

#### Contact details

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

#### Additional identifiers

Protocol serial number

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

#### Study type(s)

#### 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(s)

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

# **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

#### 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, 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

**United Kingdom** 

England

Switzerland

# Study participating centre MRC Clinical Trials Unit

London United Kingdom NW1 2DA

# Sponsor information

#### Organisation

EuroVacc Foundation (Switzerland)

#### **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, 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