ISRCTN26673492 https://doi.org/10.1186/ISRCTN26673492

# 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**
06/09/2005

**Recruitment status**
No longer recruiting

**Registration date**
21/09/2005

**Overall study status**
Completed

**Last Edited**
18/01/2011

**Condition category**
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

**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

## Primary study design
Interventional

## Study design
Randomised controlled trial

## 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

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

### 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 |