

# A phase I/II trial to compare the immunogenicity and safety of three DNA C prime followed by one NYVAC C boost to two DNA C prime followed by two NYVAC C boost

<b>Submission date</b> 22/05/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 29/06/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 11/04/2019	<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

[http://www.ctu.mrc.ac.uk/research\\_areas/study\\_details.aspx?s=2](http://www.ctu.mrc.ac.uk/research_areas/study_details.aspx?s=2)

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number  
NCT00490074

## Secondary identifying numbers

EV03 / ANRS Vac20

# Study information

## Scientific Title

A phase I/II trial to compare the immunogenicity and safety of three DNA C prime followed by one NYVAC C boost to two DNA C prime followed by two NYVAC C boost

## Acronym

EuroVacc 03 / ANRS Vac20

## Study objectives

The primary objectives are to compare the immunogenicity and safety of the three DNA-C prime and one NYVAC-C boost regimen to two DNA-C prime and two NYVAC-C boosts in healthy volunteers at low risk of HIV infection.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

UK:

1. Medicines and Healthcare Products Regulatory Agency (MHRA), 09/02/07, ref: 30860/0001/001-001
2. Gene Therapy Advisory Committee (GTAC), 26/02/2007, ref: 131

France:

3. Local ethics approval: Committee for the protection of persons [Comite de Protection des Personnes], 25/04/2007, dossier no. 07-007
4. Approval from French Health Products Safety Agency (Agence Française de Sécurité Sanitaire des Produits de Santé [AFSSAPS]), pending as of 22/05/2007

Switzerland:

5. Local ethics approval: approved by the University of Lausanne (UNIL Universite de Lausanne), ref: 233/06
6. Swiss Federal Authority (Swiss Agency for Therapeutic Products [SWISSMEDIC]), approval pending as of 22/05/2007.

Germany:

7. Ethics commission of Regensburg University (Ethik-kommission an der Universität Regensburg), ref: 06/084, approval pending as of 22/05/2007

## Study design

Randomised phase I/II multicentre international trial with a parallel group design, open to participants and investigators but blind to laboratory personnel.

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

**Study setting(s)**

Not specified

**Study type(s)**

Prevention

**Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet'

**Health condition(s) or problem(s) studied**

HIV prophylaxis

**Interventions**

Group 1: 3 x DNA HIV-C (2 x 2 ml IntraMuscular [IM] at weeks 0, 4 and 8 in right and left vastus lateralis) followed by NYVAC HIV-C (1 ml IM at week 24 in non-dominant deltoid)

Group 2: 2 x DNA HIV-C (2 x 2 ml IM at weeks 0 and 4 in right and left vastus lateralis) followed by 2 x NYVAC HIV-C (1 ml IM at weeks 20 and 24 in non-dominant deltoid)

**Intervention Type**

Drug

**Phase**

Phase I/II

**Drug/device/biological/vaccine name(s)**

DNA-C prime, NYVAC-C boosts

**Primary outcome measure**

The primary endpoints are immunogenicity and safety.

The primary immunogenicity parameter will be the presence of CD8/CD4+ T-cell responses defined according to internationally agreed criteria for evaluation of interferon-gamma (IFN $\gamma$ ) Enzyme-Linked Immunosorbent SPOT (ELISPOT) assays:

1. In response to env peptide plus at least one of the gag, pol, nef peptide pools
2. At weeks 26 and 28

The primary safety parameters will be graded and are:

1. Grade 3 or above local adverse event (pain, cutaneous reactions including induration)
2. Grade 3 or above systemic adverse event (temperature, chills, headache, nausea, vomiting, malaise and myalgia)
3. Grade 3 or above other clinical or laboratory adverse event confirmed at examination or on repeat testing, respectively.
4. Any event attributable to vaccine leading to discontinuation of the immunisation regimen.

**Secondary outcome measures**

Secondary immunogenicity and safety end-point information will be collected on all participants on the following:

1. Cellular responses:
  - 1.1. CD8/CD4+ T cell mean IFN- $\gamma$  Spot Forming Units (SFU) per million cells across the peptide pools at weeks 26 and 28
  - 1.2. CD8/CD4+ T cell mean Spot Forming Units (SFU) per million cells across the peptide pools at any week following the first immunisation including weeks 48 and 72
  - 1.3. Mean proportion of CD4/CD8+ T cells producing IL-2 and/or IFN- $\gamma$  following ex-vivo stimulation with HIV-1 peptide pools at weeks 26 and 28, 48 and 72
  - 1.4. Number of different epitopes that can be characterised
2. Antibody responses: precise assays to be determined at a later stage, but prior to unblinding of laboratory personnel
3. All grade 1 and 2 adverse events
4. All events including those considered unrelated to vaccine

**Overall study start date**

25/06/2007

**Completion date**

01/09/2009

## Eligibility

**Key inclusion criteria**

1. Age between 18 and 55 on the day of screening
2. Available for follow-up for the duration of the study (78 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; IntraUterine 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**

140

**Key exclusion criteria**

1. Pregnant or lactating
2. Clinically relevant abnormality on history or examination including history of:
  - 2.1. Grand-mal epilepsy
  - 2.2. Severe eczema
  - 2.3. Allergy to eggs or gentamicin
  - 2.4. Severe allergic diseases
  - 2.5. Liver disease with inadequate hepatic function
  - 2.6. Haematological, metabolic or gastrointestinal disorders
  - 2.7. Uncontrolled infection
  - 2.8. Autoimmune disease, 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. Positive for DNA/antinuclear (ANA) antibodies at titre considered clinically relevant by immunology laboratory
10. Grade 1 or above routine laboratory parameters
11. Unlikely to comply with protocol

**Date of first enrolment**

25/06/2007

**Date of final enrolment**

01/09/2009

**Locations****Countries of recruitment**

England

France

Germany

Switzerland

United Kingdom

**Study participating centre**

**MRC Clinical Trials Unit**

London

United Kingdom

NW1 2DA

# Sponsor information

## Organisation

EuroVacc Foundation (Switzerland)

## Sponsor details

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## Sponsor type

Industry

## Website

<http://www.eurovacc.org>

## ROR

<https://ror.org/04f2nz275>

# Funder(s)

## Funder type

Government

## Funder Name

European Commission (Belgium) (ref: QLK2-CT-2002-01431)

## 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**

**Funder Name**

French National Agency for AIDS Research (Agence Nationale de Recherches sur le SIDA [ANRS])  
(France)

## 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	26/02/2019	Yes	No