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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

Submission date
22/05/2007

Registration date
29/06/2007

Last Edited
11/04/2019

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Infections and Infestations

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

Plain English summary of protocol
http://www.ctu.mrc.ac.uk/research_areas/study_details.aspx?s=2

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00490074

Protocol serial number
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

Primary study design
Interventional

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

Study type(s)
Prevention

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(s)
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×) 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.

Key secondary outcome(s)
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× 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-× 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

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

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:
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 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/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
United Kingdom

England

France

Germany

Switzerland

Study participating centre
MRC Clinical Trials Unit
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Sponsor information

Organisation
EuroVacc Foundation (Switzerland)

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, 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

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	26/02/2019	Yes	No