ISRCTN20946776 https://doi.org/10.1186/ISRCTN20946776

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

Contact name
Dr Sheena McCormack

Contact details
MRC Clinical Trials Unit
222 Euston Road
London
United Kingdom
NW1 2DA
+44 (0)20 7670 4708
smc@ctu.mrc.ac.uk

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×) 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× 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

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 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
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
c/o Prof Peter Liljestrom
Rue de la Grotte 6
Lausanne
Switzerland
1003
+46 845 72550
peter.liljestrom@mtc.ki.se

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, Ευρωπαϊκής Επιτροπής, Европейската 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

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?
Results article	results	13/06/2008	26/02/2019	Yes	No