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The impact of therapeutic Human Immunodeficiency Virus (HIV) vaccination followed by antiretroviral therapy in patients with prolonged viral suppression

Submission date 16/11/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 16/11/2005	**Overall study status** Completed	
Last Edited 06/03/2009	**Condition category** Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HCT-44179

Study information

Scientific Title
A pilot study to determine the impact of therapeutic Human Immunodeficiency Virus (HIV) vaccination followed by a scheduled interruption of antiretroviral therapy on HIV-specific immune function by a scheduled virologic rebound in patients with prolonged viral suppression

Study objectives
Human Immunodeficiency Virus (HIV) vaccination results in delayed rebound in plasma Viral Load (pVL) after an interruption of Anti-Retroviral Therapy (ART) compared to an interruption of ART without prior vaccination.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ottawa Hospital Research Ethics Board Ottawa approved on the 22nd May 2002

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Human Immunodeficiency Virus (HIV)

Interventions
1. Remune™ (1 ml intramuscular [im]) at weeks 0, 12, and 20
2. ALVAC (1 ml im) at weeks 8, 12, 16, and 20

Trial details received 12 September 2005

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Remune™, ALVAC

Primary outcome measure
Time to virologic rebound.

Secondary outcome measures
1. To determine if, in patients with prolonged suppression of viral replication, therapeutic HIV vaccination with ALVAC alone followed by a scheduled interruption of antiretroviral therapy results in a delay in viral rebound to detectable levels (greater than 50 copies/ml) compared to a scheduled interruption of antiretroviral therapy without prior vaccination (vaccine placebo)
2. To determine if therapeutic HIV vaccination with Remune™ and ALVAC followed by a scheduled interruption of antiretroviral therapy results in a delay in the rebound of plasma HIV Ribonucleic Acid (RNA) level to 10,000 copies/ml following discontinuation of antiretroviral therapy compared to a scheduled interruption of antiretroviral therapy without prior vaccination
3. To determine if therapeutic HIV vaccination with ALVAC alone followed by a scheduled interruption of antiretroviral therapy results in a delay in the rebound of plasma HIV RNA level to 10,000 copies/ml following discontinuation of antiretroviral therapy compared to a scheduled interruption of antiretroviral therapy without prior vaccination
4. To determine if therapeutic HIV vaccination with Remune™ and ALVAC followed by a scheduled interruption of antiretroviral therapy results in a decrease in the viral set-point (steady state plasma HIV RNA level) compared to scheduled interruption of antiretroviral therapy without prior vaccination
5. To determine if therapeutic HIV vaccination with ALVAC alone followed by a scheduled interruption of antiretroviral therapy results in a decrease in the viral set-point (steady state plasma HIV RNA level) compared to scheduled interruption of antiretroviral therapy without prior vaccination
6. To determine if therapeutic HIV vaccination with Remune™ and ALVAC followed by a scheduled interruption of antiretroviral therapy results in a decrease in the magnitude of viral load rebound compared to scheduled interruption of antiretroviral therapy without prior vaccination
7. To determine if therapeutic HIV vaccination with ALVAC alone followed by a scheduled interruption of antiretroviral therapy results in a decrease in the magnitude of viral load rebound compared to scheduled interruption of antiretroviral therapy without prior vaccination
8. To determine if therapeutic HIV vaccination with Remune™ and ALVAC followed by a scheduled interruption of antiretroviral therapy results in improved HIV-specific immune function (at week 48) compared to vaccination prior to interruption of therapy (week 24)
9. To determine if therapeutic HIV vaccination with Remune™ and ALVAC followed by a scheduled interruption of antiretroviral therapy results in improved HIV-specific immune function compared to scheduled interruption of therapy without prior vaccination (week 48)
10. To determine if therapeutic HIV vaccination with ALVAC alone followed by a scheduled interruption of antiretroviral therapy results in improved HIV-specific immune function compared to scheduled interruption of therapy without prior vaccination (week 48)
11. To determine if therapeutic HIV vaccination with Remune™ and ALVAC results in improved HIV-specific immune function (in particular, HIV-specific CTL activity) compared to vaccination with ALVAC alone
12. To determine if therapeutic HIV vaccination with Remune™ and ALVAC results in improved control of viral replication (time to rebound, time to 10,000 copies/ml, magnitude of rebound,

viral set-point) compared to vaccination with ALVAC alone
13. To determine which immunologic measures correlate with the rapidity and magnitude of virologic rebound after therapy interruption
14. To determine the safety of a complex immune intervention

Overall study start date
01/04/2001

Completion date
31/03/2003

Eligibility

Key inclusion criteria
1. HIV positive CD4 greater than 500
2. Age 18 years and older, either sex
3. CD4 nadir greater than 250
4. Viral load less than 50 for greater than 2 years
5. Receiving a Protease Inhibitor (PI) or Non-Nucleoside Reverse Transcriptase Inhibitor (NNRTI)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Patients with previous Acquired Immunodeficiency Syndrome (AIDS) defining opportunistic infections, previous cancer chemotherapy or other system immunosuppressive therapy
2. Patients with concurrent infections with hepatitis C or hepatitis B or any other acute illness

Date of first enrolment
01/04/2001

Date of final enrolment
31/03/2003

Locations

Countries of recruitment
Canada

Study participating centre
Ottawa Hospital - General Campus
Ottawa
Canada
K1H 8L6

Sponsor information

Organisation
Ottawa Hospital Research Institute (Canada)

Sponsor details
501 Smyth Road
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Sponsor type
Research organisation

Website
http://www.ohri.ca/home.asp

ROR
https://ror.org/03c62dg59

Funder(s)

Funder type
Industry

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: HCT-44179)

Funder Name
Ontario HIV Treatment Network (Canada)

Alternative Name(s)

The Ontario Hiv Treatment Network, OHTN

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Canada

Funder Name
Aventis (Canada)

Funder Name
Immune Response Corp. (USA)

Funder Name
Canadian Network for Vaccines and Immunotherapeutics (CANVAC) (Canada)

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