

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
Registration date 16/11/2005	Overall study status Completed	☐ Protocol
Last Edited 06/03/2009	Condition category Infections and Infestations	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

Time to virologic rebound.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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

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Sponsor information

Organisation

Ottawa Hospital Research Institute (Canada)

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, The OHTN, the_ohtn, OntarioHIVTreatment, Ontario HIV Treatment Network (OHTN) | Toronto ON, 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

Individual participant data (IPD) sharing plan

IPD sharing plan summary