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

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

# Plain English summary of protocol

Not provided at time of registration

# 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

## 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<sup>™</sup> 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 Ottawa Canada K1H 8L6

## 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