Prediction and Pathogenesis of the Immune Reconstitution Inflammatory Syndrome.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20147

Source
Nationaal Trial Register

Brief title
IRIS

Health condition

Immune Reconstitution Inflammatory Syndrome, HIV, antiretroviral therapy (ART)

Sponsors and support

Primary sponsor: Academic Medical Center, University of Amsterdam, the Netherlands
Source(s) of monetary or material Support: UBS Optimus Foundation
University of Tuebingen
Medical Research Unit Albert Schweitzer Hospital, Lambaréné, Gabon

Intervention

Outcome measures

Primary outcome

After finalizing this observational study a nested case-control study will be performed within

this cohort, in order to:

1. Identify predicors and early diagnostic factors for the different types of IRIS, with focus on TB IRIS, cryptococcal IRIS and CMV IRIS;

2. Obtain more insight in the pathogenesis of the different types of IRIS.

Secondary outcome

1. Obtain insoght in the epidemiological characteristics of IRIS in Gabon;

2. Describe HIV related ophtalmological problems in this setting.

Study description

Background summary

Background:

Immune Reconstitution Inflammatory Syndrome (IRIS) is a term used to describe the paradoxical worsening of a pre-existing infection or the presentation of a previously undiagnosed condition in HIV infected patients soon after the commencement of antiretroviral therapy (ART).
Rationale: Prediction and diagnosis of IRIS remains complex and pathogenesis is incompletely understood.

Study design & setting:

Prospective, observational cohort with nested case-control design; 200 HIV infected patients starting ART will be followed in and around Lambaréné, Gabon.

Methods:

Patients will be followed up monthly; clinical and laboratory data will be collected and plasma will be stored for later analysis. Putative biomarkers will be assessed for their predictive value and insight will be obtained in which inflammatory pathways become activated during the different appearances of IRIS.

Study objective

The purpose of this study is:

1. To identify clinical and biological predictors for the development of IRIS in HIV infected patients and;

2. To obtain insight into the pathogenesis of this syndrome;

3. To describe the epidemiological pattern of IRIS in Gabon.

Study design

Scheduled follow up visits:

1. 2 weekly the first 2 months;

2. Month 3-12 monthly.

Intervention

Enrolment:

Extensive history & physical exam, routine chest X ray & abdominal ultrasound (signs of TB), routine haematology & chemistry & serology (hep B & TPHA), storage of plasma for later immunological assays, visual acuity, fundoscopy.

Folow up:

Extensive history & physical exam, abdominal ultrasound (monthly), routine haematology & chemistry, storage of plasma for later immunological assays, visual acuity, fundoscopy in case of detoriated visual acuity.

Contacts

Public
PO Box 22660
S. Janssen
Center for Tropical Medicine and Travel Medicine, Division of Internal Medicine,
Academic Medical Center, University of Amsterdam
Meibergdreef 9
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5664380

Scientific
PO Box 22660
S. Janssen
Center for Tropical Medicine and Travel Medicine, Division of Internal Medicine,
Academic Medical Center, University of Amsterdam
Meibergdreef 9
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5664380

Eligibility criteria

Inclusion criteria

1. Age > 18 years;

2. Informed consent;

3. Male and female patients;

4. HIV positive;

5. Eligible for ART;

6. ART naïve, or history of single dose nevirapine during previous pregnancy.

Exclusion criteria

1. No informed consent;

2. History of ART;

3. Pregnancy.

Study design

Design

Study type: Observational non invasive

Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	27-02-2012
Enrollment:	200
Type:	Anticipated

Ethics review

Positive opinion

Date:	02-03-2012
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3185
NTR-old	NTR3329
Other	Medical Research Unit - Albert Schweitzer Hospital, Lambaréné, Gabon : 06_2012_IRIS

Register ID

ISRCTN ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A