ClinicalTrials.gov
Protocol Registration System

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Optional Actions: Reset to Completed | Reset to In-Progress

Record Status: In Progress | Completed | Approved | **Released**
Released
Owned by: MOliveira **Last updated:** 06/18/2009 10:13 by ARabello
Initial release: 01/07/2008 **Last release:** 06/18/2009 Download Receipt (PDF)
Quality Assurance Review: REVIEW COMPLETED

Add **Record Log:** 01/15/08 - Descriptions for the 2 Arms are identical. Please distinguish between the Experimental and Ac

Edit **Unique Protocol ID:** PK-LPV 01
ClinicalTrials.gov ID: NCT00605098 ClinicalTrials.gov Archive Publication Status
Brief Title: Pharmacokinetics of the Tablet Formulation of Lopinavir/r as Standard and Increased Dosage During Pregnancy
Official Title: Pharmacokinetics of the Tablet Formulation of Lopinavir/r as Standard and Increased Dosage During Pregnancy in HIV-infected
Study Type: Interventional
FDA Regulated Intervention? No
IND/IDE Protocol? No
Edit **Secondary IDs:**

For completed studies: Enter Results About Results Data Entry Delayed Results Posting...

Edit **Sponsor:** Oswaldo Cruz Foundation
Collaborators: Ministery of Health, Brazil
Responsible Party: Name/Official Title: Marilia Santini de Oliveira
Organization: Instituto de Pesquisa Clínica Evandro Chagas (IPEC) - Oswaldo Cruz Foundation
Phone: 55 21 3865-9662 Ext: Email: marilia.santini@ipec.fiocruz.br
Edit **Review Board:** Approval Status: Approved Approval Number: 0036100900007
Board Name: Comitê de Ética em Pesquisa
Board Affiliation: Instituto de Pesquisa Clínica Evandro Chagas (IPEC)
Phone: 55 21 3865-9585 Email: cep@ipec.fiocruz.br
Data Monitoring Committee? No
Oversight Authorities: Brazil: National Committee of Ethics in Research
Edit **Brief Summary:** This is a multicenter, open, prospective and randomized study aimed at evaluating the pharmacokinetics of the tablet formulation

- Group 1 (standard dosage): 200/50 mg lopinavir/r, 2 tablets every 12 hours, plus two nucleoside analogs.
- Group 2 (increased dosage): 200/50 mg lopinavir/r, 2 tablets every 12 hours until the end of the second trimester of gestatio

Treatment will be initiated at any time between 14 and 30 weeks of gestation and will be maintained for at least 6 weeks after deli

The objectives are:

- To compare the pharmacokinetic parameters of the standard and increased dosage of the tablet formulation of lopinavir/r du
- To determine whether the standard and/or increased dosage of the tablet formulation of lopinavir/r during pregnancy confer
- To evaluate the transplacental passage of lopinavir/r based on the ratio between the serum concentration in maternal blood a
- To evaluate the tolerability of the two lopinavir/r dosages (standard and increased) during pregnancy.
- To describe the vertical transmission rate of HIV to the children of the pregnant women included in the study.

Detailed Description:
NOTE: Detailed Description: data not entered.

Edit **Record Verification Date:** June 2009
Overall Status: Recruiting
Study Start Date: February 2008
Primary Completion Date: February 2010 [Anticipated]
Study Completion Date: February 2010 [Anticipated]
Edit **Study Design:** Primary Purpose: Prevention
Study Phase: Phase 4
Intervention Model: Parallel Assignment
Number of Arms: 2
Masking: Open Label
Allocation: Randomized
Endpoint Classification: Pharmacokinetics Study
Enrollment: 60 [Anticipated]
Edit **Outcome Measures:** Primary Outcome Measure:
Measure: Pharmacokinetic parameters of the tablet formulation of lopinavir/r
Time Frame: Second and third pregnancy trimester and 6 weeks after delivery
Safety Issue?: No

Secondary Outcome Measures:
Measure: Ratio between the serum concentration of lopinavir/r in maternal blood and in cord blood
Time Frame: Delivery
Safety Issue?: No

Edit **Conditions:** HIV Infections
Pregnancy

Keywords: HIV
Pregnancy
Vertical disease transmission
Pharmacokinetics

Edit **Arms:** Active Comparator: 1
Experimental: 2

NOTE: An arm/group label this short may not be sufficiently descriptive, especially for later use in results.
NOTE: An arm/group label this short may not be sufficiently descriptive, especially for later use in results.

Interventions: Drug: Lopinavir / ritonavir

Lopinavir/r (200/50 mg, 2 tablets every 12 hours) plus two nucleoside analogs, starting at any time between 14 and 30 weeks

Arms: 1
Other Names:
Kaletra

Drug: Lopinavir/ritonavir

Lopinavir/r (200/50 mg, 2 tablets every 12 hours) plus two nucleoside analogs, starting at any time between 14 and 30 weeks

Arms: 2
Other Names:
Kaletra

Edit **Eligibility Criteria:** Inclusion Criteria:

- Capacity to consent and wish to participate in the study, documented by signing the specific informed consent form (ICF) o
- Age of 18 years or older.
- Pregnancy documented by urine or blood examination or ultrasound.
- Gestational age of 14 to 30 weeks calculated by ultrasound, obstetric examination or date of last menstruation, depending o
- HIV infection documented by two serological tests using different methods or analysis of HIV viral load with a positive res
- No use of antiretroviral drugs at the time of diagnosis of pregnancy (previous prophylaxis and treatment are allowed).
- Intention to continue the treatment of the study for at least 6 weeks after delivery.

Exclusion Criteria:

- History of hypersensitivity to lopinavir or ritonavir.
- Need for the concomitant use of contraindicated drugs in combination with lopinavir/ritonavir.
- Any condition that, in the opinion of the medical researchers, impairs the participation in and fulfillment of the procedures

Gender: Female

Minimum Age: 18 Years

Maximum Age:

Accepts Healthy Volunteers? No

Edit **Central Contact:** Marilia S Oliveira, MD
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Edit **Study Officials/Investigators:** Marilia S Oliveira, MD
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José Henrique S Pilotto, MD
Study Principal Investigator
Hospital Geral de Nova Iguaçu (HGNI)

Edit **Locations:** **Facility:** Instituto de Pesquisa Clínica Evandro Chagas
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Investigator: Marilia S Oliveira, MD
Role: Principal Investigator
Investigator: Beatriz J Grinsztejn, MD
Role: Principal Investigator
Investigator: Eduardo W Barroso, MD
Role: Principal Investigator

Investigator: Luciana R Pitta, MSc
Role: Sub-Investigator
Investigator: Milton Ferreira Filho, PHd
Role: Sub-Investigator
Investigator: Marlice S Marques, PHd
Role: Sub-Investigator
Recruitment Status: Recruiting

Facility: Hospital Geral de Nova Iguaçu (HGNI)
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Investigator: José Henrique S Pilotto, MD
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Role: Sub-Investigator
Recruitment Status: Recruiting

Facility: Hospital dos Servidores do Estado
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Role: Principal Investigator
Recruitment Status: Recruiting

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