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Europe - Africa Research Network for Evaluation of Second-line Therapy (EARNEST) Genital Secretions Substudy II

Submission date
18/07/2012

Recruitment status
No longer recruiting

Registration date
13/08/2012

Overall study status
Completed

Last Edited
12/05/2014

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
The aim of this study is to find out whether there is more HIV virus in the genital secretions (in other words in semen or in vaginal fluid) than in the blood of patients participating in the EARNEST study. This will help us to understand how well different second-line treatments are working in different parts of the body. We also want to find out whether the virus in the genital secretions is different to the virus in the blood. These differences may alter the way the virus in the genital secretions responds to future HIV drugs. For example, the HIV virus may have changed in a way that it will no longer respond to a certain HIV drug; this is referred to as the virus being resistant to this HIV drug.

Who can participate?
Participants in the EARNEST study (i.e., HIV-infected adults who have taken a first-line nucleoside reverse transcriptase inhibitor [NRTI]-based regimen for at least 2 years and have developed treatment failure).

What does the study involve?
Patients will be asked to provide a genital secretions sample at week 96 of the main EARNEST study and, where applicable, at the time of second-line treatment failure. Men will be asked to produce a semen sample by masturbation either at home immediately before leaving for the clinical appointment or at the clinic (depending of the availability of suitable area at the clinic for this purpose and participant preferences). Women will be given instructions on how to obtain a self-swab. Alternatively, a sample of vaginal fluids will be taken in the clinic by a doctor or a nurse using a swab by speculum examination. The latter procedure would not differ from a regular vaginal examination and should not last for longer than 10 minutes.

What are the possible benefits and risks of participating?
The study will help us to learn more about the effects of different treatments on HIV in genital secretions. At the end of the EARNEST study and after all the samples have been analysed, the participants doctor will be provided with the results of the genital secretion resistance tests. Although this is unlikely to affect the participants medical treatment, the results may be

discussed by the doctor and participant and this may be of interest to the participant. Discomfort can result from the vaginal examination, but this lasts for a short time. This will not be different from discomfort experienced in the past when having a speculum vaginal examination. The participant should be able to go home as soon as the procedure is completed.

Where is the study run from?
The study will be run at nine of the sites in Uganda that are taking part in the EARNEST study. The main site is JCRC Kampala.

When is the study starting and how long is it expected to run for?
The study started in July 2012 and recruitment will continue until January 2014.

Who is funding the study?
The Istituto Superiore di Sanita (ISS), Italy.

Who is the main contact?
Dr Nicolas Paton
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
v1.0 - 07 December 2011

Study information

Scientific Title
Determination of viral load concentrations and drug resistance profiles in genital secretions of EARNEST patients and comparison to viral load concentrations and drug resistance profiles in plasma

Acronym
EARNEST GSS II

Study objectives
Human immunodeficiency virus (HIV) is transmitted primarily through vaginal and anal intercourse, and a high concentration of HIV in semen and cervico-vaginal fluid is one factor likely to increase sexual transmission from infected individuals to their sex partners. As the genital fluids and blood are separate immunologic compartments, if HIV replication is not suppressed sufficiently it may evolve differently in the genital and blood compartments and this may result in a different spectrum of drug resistance associated mutations. This substudy of the EARNEST trial (ISRCTN37737787) therefore aims to determine the level to which the three different boosted protease inhibitor (bPI) containing second-line treatment regimens used in EARNEST are suppressing viral replication in genital secretions and to compare the magnitude of viral replication in genital secretions with the magnitude of viral replication in the plasma of these patients. For those patients with a detectable viral load the drug resistance profile in genital secretions will be compared to the drug resistance profile in plasma.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board, Uganda, 23 February 2012

Study design
Cross-sectional substudy of EARNEST

Primary study design
Observational

Study type(s)
Screening

Health condition(s) or problem(s) studied
Human immunodeficiency virus (HIV)

Interventions
This substudy is observational and there are hence no interventions. Patients will be asked to provide a genital secretions sample at week 96 of the main EARNEST trial and, where applicable, at the time of second-line treatment failure.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
This substudy of the EARNEST trial aims to determine the level to which the three different bPI-containing second-line treatment regimens used in EARNEST are suppressing viral replication in genital secretions (at week 96). For patients with a detectable viral load at week 96 the magnitude of viral replication in genital secretions will be compared with the magnitude of viral

replication in plasma and the drug resistance profile in genital secretions will be compared to the drug resistance profile in plasma.

Key secondary outcome(s))
No secondary outcome measures

Completion date
31/01/2014

Eligibility

Key inclusion criteria
1. Have been enrolled and are being followed as part of the main EARNEST trial
2. Have provided written informed consent to participate in this EARNEST substudy
3. Patients should be on the treatment regimen assigned at randomisation

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
11/07/2012

Date of final enrolment
31/01/2014

Locations

Countries of recruitment
Singapore

Uganda

Study participating centre

Department of Medicine
Singapore
Singapore
119228

Sponsor information

Organisation
Medical Research Council [MRC] Clinical Trials Unit (UK)

ROR
https://ror.org/001mm6w73

Funder(s)

Funder type
Government

Funder Name
National Institute of Health (Istituto Superiore di Sanita) [ISS] (Italy)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes