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Determination of HCV Prevalence in a HIV Patient Cohort in Phnom Penh, Cambodia (HCV-Epi)

ClinicalTrials.gov Identifier: NCT02361541

Recruitment Status : Completed
First Posted : February 11, 2015
Last Update Posted : May 16, 2016

Sponsor:
Institute of Tropical Medicine, Belgium

Collaborators:
Sihanouk Hospital Center of HOPE (SHCH), Phnom Penh, Cambodia
Universiteit Antwerpen

Information provided by (Responsible Party):
Institute of Tropical Medicine, Belgium

Study Details | Tabular View | No Results Posted | Disclaimer | How to Read a Study Record

Study Description

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Brief Summary:

Hepatitis C (HCV) is an important global public health problem, disproportionately affecting HIV positive populations. Asia and Africa account for most of the co-infection burden, but access to HCV screening and treatment is still very limited. It is expected though, with the recent therapeutic advances and increasing global advocacy efforts, that HCV treatment should become a feasible option in the near future.

Sihanouk Hospital Center of HOPE (Phnom Penh, Cambodia) is catering for one of the largest HIV cohorts of the country, followed in an ambulatory settings. In this cohort, the prevalence of HCV co-infection will be determined, as well as HCV genotype diversity and the severity of liver disease. The

researcher will also explore the performance of simple blood tests/panels as predictors of significant fibrosis and/or cirrhosis.

Patients will attend two study-visits. All adult patients of the HIV patient cohort of SHCH will be proposed HCV testing during their next HIV follow-up consultation, following the latest algorithm of the Centre for Disease Control (CDC) (May 2013). Anamnesis and clinical examination will focus, additionally to routine practice, on presence of general and HCV liver-disease related features. Laboratory analyses will include basic HIV tests (CD4), and tests for liver function such as Hepatitis B surface antigen (HbsAg) .

During the following routine HIV follow-up consultation, the results of HCV testing will be explained to the patient. If the patient is HCV negative, his/her study participation ends here. If currently infected with HCV, the clinician will repeat the HCV liver-disease (extra-hepatic & hepatic) related anamnesis and clinical examination, and prescribe additional blood tests for the non-invasive liver fibrosis/cirrhosis blood panel tests, liver and kidney function. Patients will moreover be asked to undergo a liver ultrasound and liver stiffness measurements.

Condition or disease	Intervention/treatment
Hepatitis C HIV	Procedure: HCV screening

Detailed Description:

Hepatitis C (HCV) is an important global public health problem, disproportionally affecting HIV positive populations. Asia and Africa account for most of the co-infection burden, but access to HCV screening and treatment is still very limited. The high cost and complexity of current diagnostic and treatment algorithms are major bottlenecks and the linked lack of accurate HCV prevalence estimates and treatment-need data do not allow for robust treatment advocacy and program planning. Cambodia is not an exception.

It is expected though, with the recent therapeutic advances and increasing global advocacy efforts, that HCV treatment should become a feasible option in the near future. Sihanouk Hospital Center of HOPE (Phnom Penh, Cambodia) is catering for one of the largest HIV cohorts of the country, and it is planning to engage in HCV treatment from 2014 2015 onwards, with a double objective of direct patient benefit and catalyst role at national level, as in the past when starting its antiretroviral (ARV) program.

Within this specific setting, the researchers plan to determine the prevalence of HCV co-infection, HCV genotype diversity and severity of liver disease in this HIV patient cohort, followed in an ambulatory setting. The researchers will also explore the performance of simple blood tests/panels as predictors of significant fibrosis and/or cirrhosis .

The current HCV diagnostic procedures (and tools), as applied in this study, are too expensive and resource-demanding to allow for scalability in resource limited settings. Thus, the researchers plan to set up during this study a biobank with samples of a clinically well described HIV patient population. These samples should allow constituting a well-balanced panel for evaluation of future 'more scalable' HCV diagnostic tools.

Patients will attend two study-visits. All adult patients of the HIV cohort will be proposed HCV testing during their next regular HIV follow-up consultation. HCV testing will follow the latest algorithm of the

Centre for Disease Control (CDC) (May 2013). During this same consultation, anamnesis and clinical examination will focus, additionally to routine practice ,on presence of general and HCV liver-disease related features. Laboratory analyses will also include basic HIV (CD4), and tests for liver function such as Hepatitis B surface antigen (HbsAg).

During the following routine HIV follow-up consultation (2-3 months later), the results of HCV testing will be explained to the patient. If the patient is HCV negative, his/her study participation ends here. If currently infected with Hepatitis C, the clinician will repeat the HCV liver-disease (extra-hepatic & hepatic) related anamnesis and clinical examination and prescribe additional blood tests for the non-invasive liver fibrosis/cirrhosis blood panel tests, liver and kidney function. Patients will moreover be asked to undergo a liver ultrasound and liver stiffness measurements.

The biobank will be set up with left over biological samples (whole blood plasma and serum) and comprehensive clinical information of all patients who give additional consent for this scope. Both biological samples and clinical information will be coded, to ensure confidentiality.

Study Design

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Study Type :
Observational

Actual Enrollment :
3045 participants

Observational Model:
Cohort

Time Perspective:
Cross-Sectional

Official Title:
Determination of **Hepatitis C** Prevalence, Genetic Diversity and Treatment Eligibility in an HIV Patient Cohort in Phnom Penh, Cambodia

Study Start Date :
November 2014

Actual Primary Completion Date :
April 2016

Actual Study Completion Date :
April 2016

Resource links provided by the National Library of Medicine

MedlinePlus related topics: HIV/AIDS Hepatitis Hepatitis A Hepatitis C

U.S. FDA Resources

Groups and Cohorts

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Group/Cohort	Intervention/treatment
HCV screening All adult patients of an existing HIV cohort	Procedure: HCV screening HCV antibody screening, liver function tests, full blood count and HbsAg will performed. Additional blood samples will be taken for further HCV diagnostic work-out (polymerase chain reaction (PCR) and genotyping). For patients with current HCV infection, liver ultrasound, transient elastography - Firbroscan and further lab analysis will be performed.

Outcome Measures

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Primary Outcome Measures :

1. Seroprevalence of HCV infection [Time Frame: Baseline]

   Seroprevalence of HCV infection in the HIV patient cohort

Secondary Outcome Measures :

1. Proportion of current HCV infection [Time Frame: Baseline]

   Proportion of currently infected with HCV among the HCV-IgG positive HIV patients

2. Proportion of HCV false-positives [Time Frame: Baseline]

   Proportion of HCV biologically false-positives among HCV-IgG positive screening

3. HCV genotypes [Time Frame: Baseline]

   Proportions of different HCV genotypes

4. Severity of liver disease in HCV patients [Time Frame: Baseline]

   To determine the severity of liver disease by transient elastography in this coinfected cohort

5. HCV diagnostic accuracy [Time Frame: Baseline]

   To compare the diagnostic accuracy of commonly available blood panel tests for fibrosis staging in this coinfected cohort, with liver stiffness measurement (considered as reference standard).

Biospecimen Retention: Samples Without DNA
Left over biological samples (whole blood plasma and serum)

Eligibility Criteria

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Information from the National Library of Medicine

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study:

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study:

All

Accepts Healthy Volunteers:

No

Sampling Method:

Non-Probability Sample

Study Population

All adult patients in a cohort of HIV-positive patients in Cambodia

Criteria

Inclusion Criteria:

- Adult (> or = 18 years old)
- Documented HIV positive
- In regular HIV care follow-up (min. 2 consultations in the last six months prior to the study)
- Willing and able to provide written informed consent

Exclusion Criteria:

• HIV patients with currently taking Hepatitis C treatment or with a history of prior hepatitis C treatment

Contacts and Locations

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Information from the National Library of Medicine

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT02361541***

Locations

Cambodia

Sihanouk Hospital Center of HOPE (SHCH), Cambodia
Phnom Penh, **Cambodia**

Sponsors and Collaborators

Institute of Tropical Medicine, Belgium

Sihanouk Hospital Center of HOPE (SHCH), Phnom Penh, Cambodia

Universiteit Antwerpen

Investigators

Study Director:	Anja De Weggheleire, MD	Institute of Tropical Medicine, Antwerp, Belgium
Principal Investigator:	An Sokkab, MD	Sihanouk Hospital Center of HOPE (SHCH), Cambodia

More Information

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Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

De Weggheleire A, De Baetselier I, An S, Goletti S, Suin V, Thai S, Francque S, Crucitti T, Lynen L, Van Gucht S, Kabamba BM. Challenges to Differentiate Hepatitis C Genotype 1 and 6: Results from A Field-Study in Cambodia. Infect Dis Ther. 2020 Sep;9(3):657-667. doi: 10.1007/s40121-020-00304-7. Epub 2020 May 30.

Responsible Party:
Institute of Tropical Medicine, Belgium

ClinicalTrials.gov Identifier:
NCT02361541 History of Changes

Other Study ID Numbers:
HCV-Epi

First Posted:
February 11, 2015 Key Record Dates

Last Update Posted:

May 16, 2016

Last Verified:

May 2016

Additional relevant MeSH terms:

Hepatitis C

Hepatitis

Liver Diseases

Digestive System Diseases

Hepatitis, Viral, Human

Virus Diseases

RNA Virus Infections

Flaviviridae Infections