

The relationship between stomach *Helicobacter pylori* infection and antibiotic consumption among HIV-positive individuals

Submission date 30/09/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 03/10/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 29/06/2021	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Helicobacter pylori infection, a cause of ulcers and cancer in the stomach, and ulcers in the intestines is frequent worldwide and treatment is well established in the general population. *H. pylori* infects more than half of the world's population and HIV infects nearly thirty-eight million people. HIV-infected individuals often need treatments against infections. Compared to the general population, little is known about the *H. pylori* infection among HIV-co-infected individuals.

This study aimed to evaluate the presence of and evolution of primary antibiotic resistance of *H. pylori* strains isolated amongst HIV-co-infected (case) and -uninfected (control) individuals.

Who can participate?

Any adult aged 18 or more who have a proven *H. pylori* infection by microbiology examination including antimicrobial susceptibility test and have not yet been treated for *H. pylori* infection will be invited to participate in the study.

What does the study involve?

The study involves an agreement to use results of the microbiology examination and clinical data for the research.

What are the possible benefits and risks of participating?

There will be no direct benefit from taking part although it is hoped that participants might contribute to improve our understanding. Investigators do not anticipate any risks from taking part.

Where is the study run from?

University Hospital Saint Peter in Brussels (Belgium)

When is the study starting and how long is it expected to run for?

January 2004 to December 2023.

Who is funding the study?
Principal investigator with the support of FRPD ASBL

Who is the main contact?
Dr Marcel Nkuize, marcel.nkuize@stpierre-bru.be

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

AK/07-12-77/3503

Study information

Scientific Title

Evolution of Helicobacter pylori primary antibiotic resistance in a cohort of individuals with and without HIV infection: role of antibiotics consumption

Acronym

HPPARHIV

Study objectives

To evaluate prevalence and evolution of primary antibiotic resistance of Helicobacter pylori (H. pylori) strains isolated amongst HIV-co-infected (case) and -uninfected (control) individuals. To correlate local patient's antibiotic resistance of H. pylori strains with nationwide antibiotic consumption.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 04/12/2007, Comite Local d'Ethique Hospitalier (Rue Haute 322-1000 Brussels, Belgium; +3225354481; comite_ethique@stpierre-bru.bee), ref: AK/07-12-77/3503

Study design

Observational

Primary study design

Observational

Secondary study design

Ecological study

Study setting(s)

Hospital

Study type(s)

Diagnostic

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Helicobacter pylori antimicrobial susceptibility in people with HIV infection

Interventions

Participants who fulfil inclusion criteria will be asked to give consent for the team to collect clinical information, as well as data related to *H. pylori* diagnosis.

We prospectively collected in a registry, data of local outpatients, from 1st of January, 2004 till 31st of December, 2015.

We collected Nationwide outpatient (with and without HIV infection) antibiotic consumption during the same period since 1st of January, 2004 till 31st of December, 2015.

Intervention Type

Mixed

Primary outcome measure

1. Primary *H. pylori* antibiotic resistance is evaluated by anamnesis and by microbial examination of gastric samples using disk diffusion methods (Neo-Sensitabs; Rosco, Taastrup, Denmark), and the minimum inhibitory concentration (MIC) determined by an agar dilution method at a single time point
2. Antibiotic consumption within the country during the period studied, measured by defined daily dose per 1000 inhabitants using national records

Secondary outcome measures

Measured at the time of *H. pylori* diagnosis:

1. Demographics measured using anamnesis, medical records, and hospital database
2. History of *H. pylori* treatment obtained by anamnesis, patient's medical chart, phone contact with the family medical doctor
3. HIV status measured using medical records
4. HIV viral load (measured using COBAS AmpliPrep/COBAS Amplicor HIV-1 Monitor Test v1.0, 1COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test, v2.0 real time PCR)
5. Lymphocyte T CD4 count (measured using flow cytometry, NAVIOS)
6. Chemoprevention against *Toxoplasma gondii* or *Pneumocystis jiroveci* (with trimethoprim-sulfamethoxazole) or anti-malaria drug use (including mefloquine, atovaquone, chloroquine, primaquine)
7. Consequences of infection measured by endoscopy performed using video Olympus GIF-q165, GIF-HQ 190 and gastric biopsy

Overall study start date

01/01/2004

Completion date

31/12/2023

Eligibility

Key inclusion criteria

1. No history of *H. pylori* treatment
2. Ambulatory HIV-positive and HIV-negative individuals
3. Naïve to *H. pylori* treatment
4. Aged ≥ 18 years
5. Underwent upper gastrointestinal endoscopy for any reason and for which *H. pylori* antimicrobial susceptibility test results is available

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Equal or more than 180 cases

Total final enrolment

8321

Key exclusion criteria

1. Coagulopathy
2. Partial gastrectomy
3. Does not agree to participate

Date of first enrolment

01/01/2006

Date of final enrolment

31/12/2015

Locations**Countries of recruitment**

Belgium

Study participating centre

University Hospital Saint Peter

322 Rue Haute

Brussels

Belgium

1000

Sponsor information**Organisation**

Centre Hospitalier Universitaire de Saint-Pierre

Sponsor details

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infectiousdiseases@stpierre-bru.be

Sponsor type

Hospital/treatment centre

Website

<http://www.stpierre-bru.be/en/index.html>

ROR

<https://ror.org/05cmp5q80>

Funder(s)**Funder type**

Not defined

Funder Name

Principal Investigator

Funder Name

Fond de recherche en pathologie digestive, FRDP ASBL

Results and Publications**Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal. The protocol is not available online but can be provided upon request.

Intention to publish date

31/01/2021

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/06/2021	29/06/2021	Yes	No