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

Submission date
30/09/2020

Registration date
03/10/2020

Last Edited
29/06/2021

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number
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

Study type(s)
Diagnostic

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(s)
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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
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Sponsor information

Organisation
Centre Hospitalier Universitaire de Saint-Pierre

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

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