ISRCTN16935348 https://doi.org/10.1186/ISRCTN16935348

The effects of treating Helicobacter pylori stomach infection in people with HIV infection

Submission date
24/09/2020

Recruitment status
No longer recruiting

Registration date
12/10/2020

Overall study status
Completed

Last Edited
30/09/2020

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
Helicobacter pylori (HP) 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. By contrast, little is known about how HP infection is treated among people living with HIV infection (PLWHIV). Therefore, the aim of this study is to evaluate the types of treatments used and the outcomes for PLWHIV treated for HP infection, to identify patient and disease factors that can increase the risk of treatment failure.

Who can participate?
Adult outpatients aged 18 or more who have a proven HP infection in a recent test and have not yet been treated for HP infection treatment, and who have HIV or do not have HIV, will be invited to participate in the study.

What does the study involve?
Participants will be treated for HP infection according to the current standard of care, a combination of antibiotics and proton pump inhibitor medications. Participants will be asked, using oral questionnaire about side effects (chest, digestive, general symptoms, and quality of live) during the treatment course and after cessation. Participants will then be invited back to the clinic several weeks after cessation of treatment to undergo follow-up tests in order to verify whether or not they are cured.
Participants who are HIV-infected, since October 10th, 2017 receive a support material and phone call during treatment course to hear their thoughts on the treatment side effects, and to coach their treatment.

What are the possible benefits and risks of participating?
There is no direct benefit of taking part in the study. Patients will receive the same level of care whether they choose or not choose to participate in the study, thus so there is no additional risk related to their participation in the study. The indirect benefit for the patient will be easy access to investigators and care, close follow-up with immediate support in case of side effects, and care until free of H. pylori infection

Where is the study run from?
The study will be run from University hospital Saint Pierre in Brussels (Belgium), Gastroenterology and Infectious diseases Departments

When is the study starting and how long is it expected to run for?
January 2006 to December 2023.

Who is funding the study
The study is self-funded with the support of the University Hospital Saint Pierre (Belgium).

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

Contact information

Type(s)
Public

Contact name
Dr Marcel NKuize

ORCID ID
http://orcid.org/0000-0002-7708-050X

Contact details
322 Rue Haute
Brussels
Belgium
1000
+32 25354658
marcel.nkuize@stpierre-bru.be

Type(s)
Scientific

Contact name
Dr Marcel NKuize

Contact details
322 Rue Haute
Brussels
Belgium
1000
+32 25354658
marcel.nkuize@stpierre-bru.be

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
B07620083330, B076201733646

Study information

Scientific Title
H. pylori treatment in HIV co-infected individuals with immunodepression

Acronym
OHpTHIV

Study objectives
The treatment of Helicobacter pylori (HP) infection is widely studied, in particular among the general population. The study aims to investigate HP treatment in HIV co-infected individuals to determine whether they can be treated similarly to the general population.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 08/01/2008, Comité Local d'Ethique Hospitalier (Rue Haute 322-1000 Brussels, +32 25354481; comite_ethique@stpierre-bru.be), ref: B07620083330
2. Approved 10/10/2017, Comité Local d'Ethique Hospitalier (Rue Haute 322-1000 Brussels, +32 25354481; comite_ethique@stpierre-bru.be), ref: B076201733646

Study design
Longitudinal case control single center registry

Primary study design
Observational

Secondary study design
Longitudinal study

Study setting(s)
Hospital

Study type(s)
Treatment

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 infection

Interventions
Patients included are divided into three groups:
1. Cases were HIV-positive individuals enrolled from 01/01/2006 to 31/08/2017; they receive standard of care
2. Controls were HIV-negative individuals enrolled from 01/01/2007 till 31/12/2014; they receive standard of care
3. Consecutive HIV-positive individuals recruited prospectively from 10/10/2017 to 10/09/2019; they receive HP treatment based on microbiology test only, a writing support material and phone call during the treatment course

The study will run from inclusion until approximately 6 weeks after treatment completion.

Types of treatment and drug dose:
1. Standard triple therapy: a PPI plus two antibiotics (amoxicillin (AMX) 1000 mg, clarithromycin (CLA) 500 mg, or metronidazole (MET) 500 mg) twice daily for 7 to 14 days
2. Sequential therapy: a PPI plus AMX 1000 mg twice daily for 5 days followed by a PPI plus CLA 500 mg and MET 500 mg twice daily for 5 days
3. Quadruple therapy pharmacy preparation of capsules: including tetracycline (TET)-chlorhydrate 500 mg plus colloidal bismuth sub-citrate 500 mg four times daily, MET 500 mg three times daily, and PPI twice daily for 10 days
4. Another quadruple therapy: single pill formulation: containing bismuth sub-citrate 140 mg /TET-chlorhydrate 125 mg/MET 125 mg (three pills to take four times daily) plus one PPI (twice daily) for 10 days
5. Concomitant therapy (CoT): PPI plus three antibiotics (AMX 1000 mg, CLA 500 mg, MET 500 mg) twice daily for 14 days. Proton pump inhibitors will be esomeprazole 40 mg, lansoprazole 30 mg, omeprazole 20 mg or 40 mg, pantoprazole 40 mg or rabeprazole 20 mg

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
1. Amoxicillin 2. Bismuth 3. Clarithromycin 4. Levofloxacin 5. Metronidazole 6. Tetracycline 7. Esomeprazole 8. Lansoprazole 9. Omeprazole 10. Rabeprazole 11. Pantoprazole

Primary outcome measure
Among of HIV-co-infected individuals:
Rate of first-line HP treatment failure (defined by a positive urea breath test performed at least 6 weeks after the treatment completion and 3 weeks after withdrawal of proton pump inhibitors)

Secondary outcome measures
Information collected from the patient during the study:
1. Types of first-line HP treatment
2. Demographics and clinical parameters
3. Immune function

Exploratory outcome measures:
1. Type, duration, year of HP treatment will be collected and recorded at the beginning of the treatment using Excel file
2. Demographics: age measured in years, gender and ethnicity, based on the patient's self-identification and geographic area of origin, and if necessary using hospital administrative database, body mass index measured in kg/m2, alcohol and tobacco habits measured using binary response. Co-medication evaluated by anamnesis, medical file and data provided by the family doctor. Those parameters will be collected at the time of HP infection treatment initiation. Adverse effects, tolerability will be collected "on" treatment using adapted questionnaire from de Boer W.A et al (1996): type and severity and ability to interfere with daily activity and treatment continuation. Compliance will be assessed by counting the pills returned by the patients after ending therapy
3. Immune function notably lymphocyte T CD4 count (measured using flow cytometry, NAVIOS) and HIV viral load (measured using COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test, v2.0 real time PCR), and HIV treatment data (composition, duration) will be collected at or close to the time of HP infection treatment initiation
4. Outcome: will be evaluated mainly by urea breath (using mass spectometry), eventually by microbiology and pathology examination of gastric samples, each performed at least 6 weeks after the withdrawal of antibiotics and 3 weeks after withdrawal of proton pump inhibitors

Overall study start date
01/01/2006

Completion date
31/12/2023

Eligibility

Key inclusion criteria
1. Age equal or more than 18 years
2. H. pylori infection proven either by culture with antimicrobial susceptibility test or by pathology examination of gastric samples obtained through upper gastrointestinal endoscopy
3. No prior history of HP treatment

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
500

Key exclusion criteria

1. Pregnancy
2. Partial or total gastrectomy
3. Disagreement to participate
4. Prior history of HP treatment
5. History of anti-HP antibiotic allergy
6. End-stage organ dysfunction (liver disease or kidney disease with dialysis)

Date of first enrolment
01/01/2008

Date of final enrolment
31/12/2022

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
322 Rue Haute
Brussels
Belgium
1000
+32 25354109
infectiousdiseases@stpierre-bru.be

Sponsor type
Hospital/treatment centre

Website
https://www.stpierre-bru.be/

ROR

https://ror.org/05cmp5q80

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Funder Name
Centre Hospitalier Universitaire de Saint-Pierre

Results and Publications

Publication and dissemination plan
Planned publication of results in a high impact-factor journal.

Intention to publish date
30/03/2021

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 (Nkuize M. at marcel.nkuize@stpierre-bru.be) six months after the publication of study results. Datasets are confidential and any data sharing will have to go through the Medical Research Ethic Committee at University Hospital Saint Peter.

IPD sharing plan summary
Available on request