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Effectiveness of tailored and conventional therapy in H. pylori treatment of Vietnamese patients

Submission date
01/03/2022

Recruitment status
No longer recruiting

Registration date
02/03/2022

Overall study status
Completed

Last Edited
02/03/2022

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
Infection with Helicobacter pylori (H. pylori) bacteria can lead to a peptic ulcer (a sore on the lining of the stomach, small intestine or food pipe). Tailored therapy has been reported to achieve a higher eradication rate than conventional therapy in treating patients infected with H. pylori who have not been treated before. However, there is little information about its effectiveness in patients who previously failed treatment. The aim of this study is to evaluate the H. pylori eradication effectiveness of bismuth quadruple therapy and tailored therapy based on antibiotic susceptibility and the CYP2C19 genotype of Vietnamese patients after treatment failure.

Who can participate?
Patients aged over 18 years old with peptic ulcers who have a record of H. pylori treatment failure and a confirmed infection

What does the study involve?
Participants are randomly allocated into two groups: conventional therapy and tailored therapy. The tailored group are tested for their CYP2C19 genotype and susceptibility for five antibiotics (amoxicillin, clarithromycin, levofloxacin, tetracycline and metronidazole). The conventional group receive a bismuth quadruple therapy while the tailored group are treated with adjusted medications based on their test results. All participants are treated for 14 days and H. pylori eradication is assessed by a breath test after 4 weeks of follow-up.

What are the possible benefits and risks of participating?
Participants in the tailored group will receive adjusted regimens based on their results of CYP2C19 polymorphism and antibiotic susceptibility that helps to reduce the risk of further treatment failure. All patients may experience side effects from taking medications such as loss of appetite, nausea, fatigue, heartburn, upset stomach, black stools, and a bitter taste.

Where is the study run from?
University Medical Center, Ho Chi Minh City (Viet Nam)

When is the study starting and how long is it expected to run for?
September 2014 to June 2017

Who is funding the study?
Department of Science and Technology of Ho Chi Minh City (Viet Nam)

Who is the main contact?
Dr Diem My Vu
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Contact information

Type(s)
Principal investigator

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Additional identifiers

Protocol serial number
256/QĐ-SKHCN

Study information

Scientific Title
Tailored versus conventional therapy in rescue treatment of Vietnamese patients with Helicobacter pylori: a randomized control trial

Study objectives
Tailored therapy has been reported to achieve a higher eradication rate than conventional therapy in treating naive patients infected with H. pylori. However, there is sparse information about its effectiveness in patients who previously failed treatment. Therefore, this study evaluated the H. pylori eradication efficacy of bismuth quadruple therapy and tailored therapy based on antibiotic susceptibility and CYP2C19 genotype of Vietnamese patients after treatment failure.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/12/2014, The Ethics Committee of University of Medicine and Pharmacy at Ho Chi Minh City (217 Hong Bang St, District 5, Ho Chi Minh City, Vietnam; +84 (0)838535159; nghiencuukhoahoc@ump.edu.vn), ref 395/ĐHYD-HĐ

Primary study design
Interventional

Study design
Randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Helicobacter pylori infection

Interventions
Block randomization with a block size of 10 is used for randomly distributing participants into the two study groups. Patients are randomly assigned to the control group or the tailored group in a 1:1 ratio. The tailored group undergo a gastrointestinal endoscopy, biopsies are collected for the isolation of H. pylori and they undergo an analysis of CYP2C19 polymorphism and susceptibility testing for five antibiotics (amoxicillin, clarithromycin, levofloxacin, tetracycline, metronidazole). The conventional group receive a bismuth quadruple regimen while the tailored group is treated with adjusted medications based on their test results. All patients are treated for 2 weeks and supervised for 4 weeks after the treatment is finished. Data are collected every 2 weeks to assess patient compliance and the occurrence of side effects. A urea [14C] breath test (PY test) is performed at week 6 for determining H. pylori eradication.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Amoxicillin, clarithromycin, levofloxacin, tetracycline, metronidazole, esomeprazol, bismuth

Primary outcome(s)
H. pylori eradication determined using a urea [14C] breath test (PY test) performed at week 6

Key secondary outcome(s)
1. Antibiotic resistance measured using minimum inhibitory concentration (MIC) test at the first hospital visit after patient enrolment
2. CYP2C19 polymorphism genotyping using real-time PCR and sequencing at the first hospital visit after patient enrolment

Completion date

13/06/2017

Eligibility

Key inclusion criteria
1. Aged 18-95 years old
2. Had a confirmed H. pylori infection by urea breath test or PY test
3. Had a history of H. pylori treatment failure

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
95 Years

Sex
All

Total final enrolment
540

Key exclusion criteria
1. Younger than 18 years old
2. Received a treatment of antibiotics, antacids, or bismuth-containing drugs within 1 month before the study
3. Had gastric cancer or gastrointestinal bleeding

Date of first enrolment
01/04/2015

Date of final enrolment
31/03/2017

Locations

Countries of recruitment
Viet Nam

Study participating centre

University Medical Center, Ho Chi Minh City
215 Hong Bang Street, District 5
Ho Chi Minh
Viet Nam
70000

Sponsor information

Organisation
Department of Science and Technology of Ho Chi Minh City

Funder(s)

Funder type
Government

Funder Name
Department of Science and Technology of Ho Chi Minh City

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from Dr Diem My Vu (diemmyvu@ump.edu.vn or diemmyvu@gmail.com) on reasonable request. The data will be available for 5 years after trial completion. Other data (e.g. demographic data, health records, experimental data) collected during the trial will be available upon request and with patient agreement.

IPD sharing plan summary
Available on request

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