

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

Submission date 01/03/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 02/03/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 02/03/2022	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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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Study website
<http://www.umptransmed.com>

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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; nghienquukhoahoc@ump.edu.vn), ref 395/DHYD-HĐ

Study design

Randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

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

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 measure

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

Secondary outcome measures

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

Overall study start date

05/09/2014

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

Age group

Mixed

Lower age limit

18 Years

Upper age limit

95 Years

Sex

Both

Target number of participants

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

Sponsor details

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Sponsor type

Government

Website

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Funder(s)**Funder type**

Government

Funder Name

Department of Science and Technology of Ho Chi Minh City

Results and Publications**Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

01/09/2022

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