ISRCTN62400496 https://doi.org/10.1186/ISRCTN62400496

Helicobacter pylori eradication - which is the best regimen: classic triple therapy or sequential therapy?

Submission date
02/09/2013

Recruitment status
No longer recruiting

Registration date
07/10/2013

Overall study status
Completed

Last Edited
17/12/2020

Condition category
Digestive System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Helicobacter pylori (H. pylori) is a bacterium related to peptic ulcers and gastric cancer. Elimination of this bacterium is important to reduce the risk of diseases mentioned above. This study compares the effectiveness of two different eradication treatments.

Who can participate?
Patients with indigestion caused by H. pylori infection can participate in the study.

What does the study involve?
Patients will be randomly allocated to one of two treatment groups. Patients have to take pills of two different drug combinations based on the group to which they are allocated for 10 days.

What are the possible benefits and risks of participating?
Patients may benefit from indigestion relief, cure of the ulcers and prevention of gastric cancer. The risks due to the procedures and the side effects due to the drugs are low.

Where is the study run from?
The study is run in the outpatients gastroenterological unit of Hospital das Clinicas, São Paulo, Brazil.

When is study starting and how long is it expected to run for?
The study started in March 2013 and will finish in December 2013.

Who is funding the study?
The study is funded by Medley S.A. Indústria Farmacêutica and Hospital das Clínicas da Faculdade de Medicina da USP, Brazil.

Who is the main contact?
Dr Fernando Marcuz Silva
fernando.marcuz@hc.fm.usp.br

Contact information

Type(s)
Scientific

Contact name
Dr Jaime Eisig

Contact details
Rua Albuquerque Lins 848, comp 112
Sao Paulo
Brazil
01230-000

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Helicobacter pylori eradication: sequential versus classic triple therapy: a prospective randomized controlled double-blind study

Study objectives
Due the increasing antibiotic resistance, sequential therapy can be an alternative to classic regime, in Helicobacter pylori eradication. But, in Brazil there are no works verifying the efficacy of the sequential and it is possible that classic regime still has good efficacy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Sao Paulo Ethical Commitee, 08/05/2013

Study design
Prospective randomized controlled double-blind study

Primary study design
Interventional

Secondary study design

Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Epigastric pain with normal or altered endoscopy

Interventions
100 peptic ulcer or functional dyspepsia patients randomized to two eradication regimens - two arms Helicobacter pylori eradication study:
1. Amoxicillin + clarithromycin + lansoprazole for 10 days
2. Amoxicillin + lanzoprazole 5 days, followed by clarithromycin + tinidazole + lansoprazole 5 days
Route of administration: Oral
The pills are packed in blisters and the control is done by counting of the pills from one of the investigators.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Amoxicillin, clarithromycin, lansoprazole and tinidazole

Primary outcome measure
1. Eradication rates
2. Cure rates will be achieved by endoscopy or UBT performed two months after the end of the treatment

Secondary outcome measures
Adverse effects are assessed by a questionnaire at the final visit

Overall study start date
12/08/2013

Completion date
31/12/2013

Eligibility

Key inclusion criteria

1. Outpatients with organic or functional dyspepsia
2. Aged between 18 and 80 years
3. Helicobacter pylori diagnosis confirmed by histology, rapid urease test or urea breath test (UBT)
4. No previous eradication history
5. Patients need to sign and understand the informed consent term

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

Total final enrolment
100

Key exclusion criteria
1. Chronic or regular use of anabolic androgenic steroids (AAS) or non-steroidal anti-inflammatory drug (NSAID)
2. Recent antibiotic use (at least 30 days) before the study inclusion or before eradication control
3. Complicated peptic ulcer (Forrest I, Forrest II), bulbar stenosis
4. Pregnant or breastfeeding women
5. Previous gastric surgery
6. Consumptive renal, cardiac, hepatic insuficiency diseases

Date of first enrolment
12/08/2013

Date of final enrolment
31/12/2013

Locations

Countries of recruitment
Brazil

Study participating centre

Rua Albuquerque Lins 848, comp 112
Sao Paulo
Brazil
01230-000

Sponsor information

Organisation
Hospital das Clínicas da Faculdade de Medicina da USP (Brazil)

Sponsor details
Rua Dr. Ovídio Pires de Campos
225 - Cerqueira
César
Sao Paulo
Brazil
05403-010

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03se9eg94

Funder(s)

Funder type
Industry

Funder Name
The drugs are a courtesy of Medley S.A. Indústria Farmacêutica, Brazil but the tests are paid by Hospital das Clínicas da Faculdade de Medicina da USP, Brazil in routine care of patients with gastric diseases

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2015	17/12/2020	Yes	No