

Randomised multicentric controlled clinical trial to compare efficacy of rifabutin-based therapy versus quadruple therapy as second-line treatment in the infection of *Helicobacter pylori*

Submission date 20/03/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 25/04/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 17/09/2008	Condition category Digestive System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2004-001320-20

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

HP-R/2003

Study information

Scientific Title

Study objectives

Rifabutin-based therapy will achieve an eradication rate of Helicobacter infection similar to quadruple therapy as a second-line treatment.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved on 23/04/2004 by "Comité Autonómico de Ensayos Clínicos de Andalucía" and authorised by " Agencia Española de Medicamentos y Productos Sanitarios" with EudraCT ref 2004-001320-20.

Study design

Randomised multicentric open clinical trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Helicobacter pylori infection after failed first treatment

Interventions

Allocated the patients to two options of therapy:

1. Experimental: omeprazol 20 mg/12 hours and amoxicillin 1 gr/12 hours and rifabutin 150 mg /12 hours for seven days
2. Control therapy: omeprazol 20 mg/12 hours and bismuth 120 mg/6 hours and metronidazole 500 mg/8 hours and tetracycline 500 mg/6 hours for seven days

The duration of follow up was 45 days after medications.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Rifabutin, omeprazole, metranidazole, tetracycline and bismuth

Primary outcome measure

Efficacy assessed by urea breath test, measured 45 days after completion of the treatment.

Secondary outcome measures

Adverse events at the completion of the treatment, and 45 days after the completion of the treatment.

Overall study start date

01/09/2004

Completion date

01/12/2005

Eligibility

Key inclusion criteria

Patients in whom *Helicobacter pylori* infection persisted after a triple therapy treatment were included.

Participant type(s)

Patient

Age group

Adult

Sex

Not Specified

Target number of participants

206

Key exclusion criteria

1. Withheld consent
2. Had initially been treated by the "Test and Treat" procedure, or a baseline endoscopy was not obtained
3. Fulfilment of the treatment regimen and attendance at follow-up appointments could not reasonably be expected
4. Human Immunodeficiency Virus (HIV) positive status
5. Active alcoholism
6. Addiction to drugs
7. Age less than 18 years or more than 75 years
8. The suspicion of tuberculous infection

9. Either because of a positive intradermal reaction to Mantoux and compatible thorax radiography, or if the patient had previously received tuberculostatic treatment, or a known allergy to any of the components of either of the two treatment regimens
10. Received quadruple therapy as first-line treatment, or any other treatment including bismuth (e.g., ranitidine bismuth citrate), or antibiotics during the previous month
11. Severe associated diseases:
- a. cardiac insufficiency
 - b. respiratory insufficiency
 - c. chronic kidney insufficiency
 - d. hepatic insufficiency
 - e. advanced neoplastic diseases
12. Pregnant or lactating

Date of first enrolment

01/09/2004

Date of final enrolment

01/12/2005

Locations

Countries of recruitment

Spain

Study participating centre

Unidad de Aparato Digestivo

Marbella

Spain

29603

Sponsor information

Organisation

Andalusian Digestive Disease Society (Sociedad Andaluza de Patología Digestiva) (Spain)

Sponsor details

A7 Km 187 s/n

Marbella

Spain

29603

Sponsor type

Hospital/treatment centre

Website

Funder(s)

Funder type

Government

Funder Name

Andalucia Health Committee (Consejería de Salud de la Junta de Andalucía) (Spain)

Funder Name

Fundación Hospital Costa del Sol de Marbella (Spain)

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	25/07/2007		Yes	No