ISRCTN81058036 https://doi.org/10.1186/ISRCTN81058036

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

Registration date
25/04/2007

Overall study status
Completed

Last Edited
17/09/2008

Condition category
Digestive System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Clinical Trials Information System (CTIS)
2004-001320-20

Protocol serial number
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 Clinicos 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

Study type(s)
Treatment

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(s)
Efficacy assesed by urea breath test, measured 45 days after completion of the treatment.

Key secondary outcome(s))
Adverse events at the completion of the treatment, and 45 days after the completion of the treatment.

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

Healthy volunteers allowed
No

Age group
Adult

Sex
Not Specified

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 neoplasic 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)

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

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