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Helicobacter Pylori Eradication

Submission date	Recruitment status	[_] Prospectively registered
23/11/2014	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
10/12/2014	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/05/2021	Infections and Infestations	

Plain English summary of protocol

Background and study aims
Helicobacter pylori (HP) is a bacteria that can infect the stomach lining and duodenum (first part of the intestine). Once infected, unless treated, a person is infected for life. Most people have no symptoms (asymptomatic). However, it can cause ulcers, indigestion, nausea and vomiting, extreme tiredness (fatigue) and tarry stools. Over time,, it can also increase the risk of stomach cancer. Patients with symptoms can be offered eradication therapy, which consists of a combination of antibiotics. HP eradication is still a problem, however, as desired levels of treatment have not been achieved yet. Here, we want to find out whether the success rate of HP eradication is lower in a country where the rate of HP infection is high and is there any benefit to treating asymptomatic HP-positive (infected) partners at the same time as symptomatic HP-positive patients.

Who can participate?
Adult symptomatic HP-positive patients and their asymptomatic HP-positive partners.

What does the study involve?
The patients are randomized into two groups. Those in group 1 are treated for HP infection and so are their partners. Those in group 2 are also treated but their partners are not. The treated offered to all participants is a combination therapy of levofloxacin 500 mg daily, amoxicillin 1g b. i.d and lansoprazole 30 mg b.i.d (LAL) for ten days. The presence of HP bacteria is then tested for by a stool antigen test six weeks later.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
Recep Tayyip Erdoğan (RTE) University, Gastroenterology Polyclinic (Turkey)

When is the study starting and how long is it expected to run for?
January 2013 to November 2014

Who is funding the study?
Recep Tayyip Erdoğan (RTE) University, Gastroenterology Polyclinic (Turkey)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
210247

Study information

Scientific Title
Is There Any Advantage of Treating Partners in Helicobacter Pylori Eradication?

Study objectives
Effects of partners and reinfection on H.pylori eradication were studied.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee RTE University , 17/10/2014, ref. 2014/132

Study design
Single-centre, prospective, controlled.

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 the contact details below to request a patient information sheet

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

Interventions
The participants were randomised into two groups:

Group 1: HP-positive patients and HP-positive partners were treated with levofloxacin 500 mg daily, amoxicillin 1g b.i.d and lansoprazole 30 mg b.i.d (LAL) for ten days.
Group 2: Only the HP-positive patients were treated with levofloxacin 500 mg daily, amoxicillin 1g b.i.d and lansoprazole 30 mg b.i.d (LAL) for ten days.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
1. Levofloxacin 2. Amoxicillin 3. Lansoprazole

Primary outcome measure
Eradication success rate

Secondary outcome measures
Re-infection rate between partners

Overall study start date
01/01/2013

Completion date
30/11/2014

Eligibility

Key inclusion criteria

Helicobacter pylori positive patients and their partners

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
100

Total final enrolment
206

Key exclusion criteria
People who are Helicobacter pylori negative

Date of first enrolment
13/01/2013

Date of final enrolment
31/10/2014

Locations

Countries of recruitment
Türkiye

Study participating centre
Recep Tayyip Erdoğan (RTE) University, Gastroenterology Polyclinic
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Sponsor information

Organisation
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/0468j1635

Funder(s)

Funder type
University/education

Funder Name
Recep Tayyip Erdogan University (Turkey)

Results and Publications

Publication and dissemination plan

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/01/2015	10/05/2021	Yes	No