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Comparison of how well allopathic and herbal medicine work for the treatment of Entamoeba histolytica

Submission date
19/07/2012

Recruitment status
No longer recruiting

Registration date
30/07/2012

Overall study status
Completed

Last Edited
13/10/2016

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Amoebiasis is an infection of the gut caused by a parasite called Entamoeba histolytica, which is found in most tropical areas. Infections occur in both the intestine and (in people with symptoms) in the tissue of the intestine and/or liver. As a result, two different classes of drugs are needed to treat the infection, one for each location, such as metronidazole and diloxanide furoate. It is claimed that a herbal medicine (Endemali) treats both types of infection with very few side effects. The aim of this study is to find out which of the two treatments is better with respect to effectiveness and side effects in order to find an alternative treatment for E. histolytica, which is developing growing resistance against the traditional medicine.

Who can participate?
Patients aged 5 to 60 with amoebiasis

What does the study involve?
Participants are randomly allocated to one of two treatment groups. One group was treated with a combination of metronidazole and diloxanide furoate three times a day for 5 days. The other group was treated with Endemali four times a day for 10 days. During the course of treatment, participants are checked for the development of side effects or any other complications. At the end of the study participants are checked for the presence or absence of E. histolytica.

What are the possible benefits and risk of the participating?
This study could help patients in the future by providing an option of a drug which is more effective and has fewer side effects. Participants are provided with treatment and their investigations free of charge. Those for whom the treatment did not work are further investigated and provided with other treatment options without charge. There is a chance of developing side effects and the drugs may not work.

Where is study run from?
Hamdard University (Pakistan)

When is the study starting and how long is it expected to run for?
January to December 2008

Who is funding the study?
Hamdard University (Pakistan)

Who is the main contact?
1. Prof. Dr Muhammad Irfanullah Siddiqui (irfan7255@yahoo.com)
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Contact information

Type(s)
Scientific

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Protocol serial number
001

Study information

Scientific Title
A randomized double blind study to find out whether there is any difference in the efficacy and side effects of Endemali® and a combination of diloxanide furoate and metronidazole

Study objectives
There are two hypothesis simultaneously tested:
1. It is hypothesized that there is some difference between Endamali (a herbal medicine) and a combination of metronidazole and diloxanide furoate with respect to efficacy and side effects. (Two-tailed)

Null hypothesis: There is no difference in the efficacy of Endamali and a combination of metronidazole and diloxanide furoate with respect to efficacy.

2. It is hypothesized that there is some difference between Endamali (a herbal medicine) and a combination of metronidazole and diloxanide furoate with respect to side effects. (Two-tailed)

Null hypothesis: There is no difference in the efficacy of Endamali and a combination of metronidazole and diloxanide furoate with respect to side effects.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Hamdard University, 16/01/2007, ref: CMHCMD/001/2007

Primary study design
Interventional

Study design
Double-blind randomized parallel bi-centric study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Amoebiasis

Interventions
To determine the sample size, we used α <0.05 and power of study as 90%. The effect size considered to be clinically significant, was a 0.15 difference between two groups based on a pilot study. Hypothesis test for two population proportion with two sided test was calculated with the help of WHO Manual. A total of 101 sample size was calculated for each group. The total 202 patients were divided into 21 blocks. The block technique used has already been described in the application sent to you, in which we used the block of 10 in order to have almost equal number of participants in both group. Out of the 10 sheet written for each block, five were marked "treatment group 1"(TR1) and rest as "treatment group 2" (TR2). Each eligible participant was invited to pick blindly one sheet out of 10 available. Once the five patients of one treatment group were complete, rest of the patients were allocated to the other group e.g. in one draw first patient picked TR1, second also picked TR1, 3rd picked TR2, 4th picked TR1 5th picked TR2, 6th picked TR2, 7th picked TR2, 8th picked TR1, 9th picked TR1 and then 10th was automatically allocated to TR2. Once a sheet was picked, after noting the group allocation, it was put back in the drawer to make it 10 again so that every patient has an equal probability of being allocated to any of the group.

Treatment group 1: combination of metronidazole + diloxanide furoate available in Pakistan with brand name "Entamizole DS". This tablet contains metronidazole 400mg + diloxanide furoate 500mg. Entamizole DS was given 3 times a day for 5 days.

Treatment group 2: Endemali®, a herbal product, available in 4gm sachet, containing Boswellia glabra 270.9 mg, Kaolinum ponderosum 255 mg, Ocimum pilosum 580 mg, Pistacia terbinthus 116.1 mg, Plantago ispagula 812.7 mg, Vateria indica 232.2mg sweeting agent q.s. Endemali® was given 4 times a day for 10 days.

Intervention Type
Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)
Diloxanide furoate, metronidazole

Primary outcome(s)
Efficacy at baseline and 5 days after stopping the treatment

Key secondary outcome(s)
1. Side effects
2. Association of age with efficacy
3. Association of sex with efficacy
4. Association of age with side effects
5. Association of sex with side effects
Measured at baseline and immediately after completion of course of treatment.

Completion date
31/12/2008

Eligibility

Key inclusion criteria
1. All the confirmed cases of amoebiasis and between the ages of 5 and 60 years were invited to be included in the study
2. Willing to be assigned to any of the two treatment groups

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
All those who had multiple problems

Date of first enrolment
01/01/2008

Date of final enrolment
31/12/2008

Locations

Countries of recruitment

Pakistan

Study participating centre
House No A-4 ST-33
Karachi
Pakistan
75850

Sponsor information

Organisation
Hamdard University (Pakistan)

ROR
https://ror.org/01zrv0z61

Funder(s)

Funder type
University/education

Funder Name
Hamdard University (Pakistan)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration