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The HALT Latent Tuberculosis study

Submission date
19/10/2012

Recruitment status
No longer recruiting

Registration date
26/02/2013

Overall study status
Completed

Last Edited
25/01/2021

Condition category
Infections and Infestations

[X] Prospectively registered

[_] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Within the UK, completion rates for latent tuberculosis infection (LTBI) treatment regimens are known to be poor. A recent paper described a novel LTBI treatment regimen of Rifapentine /Isoniazid with high completion rates. The aim of this study is to compare completion rates between this novel regimen and a Rifinah regimen and provide useful data to inform future practice. The value for money of this approach is assessed.

Who can participate?
Male or non-pregnant, non-nursing, females, aged between 16 and 65, who test positive for LTBI but do not have active tuberculosis disease

What does the study involve?
Participants are randomly allocated to either twice daily Rifinah or weekly Rifapentine and Isoniazid for 3 months. Treatment adherence and adverse reactions are monitored every month through clinic appointments and for 1 month after treatment completion.

What are the possible benefits and risks of participating?
Participants could reduce their risk of developing active tuberculosis by being treated. Possible side effects include hepatoxicity (damage of the liver). These would be monitored during the study and the treatment would be stopped if clinically indicated.

Where is the study run from?
University College London (UK)

When is the study starting and how long is it expected to run for?
May 2014 to May 2015

Who is funding the study?
Department of Health (UK)

Who is the main contact?
Prof. Ibrahim Abubakar
i.abubakar@ucl.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Ibrahim Abubakar

ORCID ID
http://orcid.org/0000-0002-0370-1430

Contact details
University College London
Research Department of Infection and Population Health
4th floor Mortimer Market, off Capper Street
London
United Kingdom
WC1E 6JB
+44 (0)20 7679 0954
i.abubakar@ucl.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
12/0426

Study information

Scientific Title
The HALT LTBI study: Phase IV multi-site, unblinded, randomised trial of prophylactic Rifapentine /Isoniazid versus Rifampicin/Isoniazid (Rifinah) for latent tuberculosis infection (LTBI)

Study objectives
Completion rates for individuals treated with Rifapentine/Isoniazid will be higher than for those treated with Rifinah.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London, Brent, 29/11/2013, ref: 13/LO/1666

Study design

Pilot of a randomised controlled trial

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 to request a patient information sheet

Health condition(s) or problem(s) studied
Latent tuberculosis infection

Interventions
Random allocation to either Rifinah (300mg Rifampicin plus 150mg Isoniazid, two daily) or Rifapentine and Isoniazid (3 months, 12 weekly doses); monthly follow-up for the duration of treatment and one month after treatment completion.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Rifampicin, isoniazid, rifapentine

Primary outcome measure
1. Completion of treatment regimen
2. Associated health economics to determine cost effectiveness of the intervention

Secondary outcome measures
Adverse effects of treatment for LTBI

Overall study start date
01/05/2014

Completion date
30/06/2017

Eligibility

Key inclusion criteria
1. Male or non-pregnant, non-nursing, female adults aged between 16 years 0 days and 64 years 364 days at enrolment
2. Individuals at high risk for developing tuberculosis but without evidence of active tuberculosis. High-risk is defined on the basis of a positive Interferon Gamma Release Assay (IGRA)
3. People with no evidence of active tuberculosis who have a positive IGRA as defined above
4. Willing and able to provide written informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
100

Total final enrolment
52

Key exclusion criteria
Current exclusion criteria as of 31/03/2014:
1. Patients unable to give consent
2. Pregnant or breastfeeding women
3. Patients whose weight is under 45 kg
4. Allergies to any of the study drugs or excipients contained in preparations of these medicines
5. Patients requiring medications that cannot be safely taken with the study drugs (see Appendix 2)
6. Any medical condition deserving priority of treatment (such as: porphyria, malabsorption syndromes, Clostridium difficile-associated diarrhoea and other conditions)
7. HIV infection
8. Individuals with known liver disease, defined as LFT (ALT/AST/bilirubin) over upper limit of normal (ULN) at baseline (one abnormal value prevents the patient from participating in the study)
9. Clinical diagnosis of cirrhosis (jaundice, hematemesis, ascites or previous episodes of liver encephalopathy)
10. Chronic/active hepatitis B or hepatitis C virus infection
11. High-risk drinking, according to the Department of Health criteria (regularly drinking more than 8 units a day or 50 units a week for men; regularly drinking more than 6 units a day or 35 units a week for women)
12. Previous treatment for TB or LTBI
13. Individuals who would usually be offered LTBI treatment under Directly Observed Therapy (DOT) because of their mental or social disabilities
14. Use of another experimental investigational medicinal product that is likely to interfere with the study medication within 3 months of study enrolment

Previous exclusion criteria:
1. Females of childbearing potential must be willing to use an effective method of contraception
2. Females of childbearing potential must have a negative pregnancy test within 7 days prior to being registered for trial treatment
3. Females must not be breastfeeding
4. Allergies to Rifapentine, Isoniazid, Rifampicin or excipients contained in the preparations of these medicines
5. Patients requiring medications that cannot be safely taken with the study drugs
6. High risk drinking, according to the Department of Health criteria
7. Those who are HIV positive
8. Individuals who already have significant liver disease
9. Those who would not be eligible for LTBI treatment under the American Thoracic Society Criteria
10. Individuals who would usually be offered LTBI treatment under Directly Observed Therapy (DOT)

Date of first enrolment
01/05/2014

Date of final enrolment
31/05/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University College London
London
United Kingdom
WC1E 6JB

Study participating centre
Barts Health, Newham University Hospital
London
United Kingdom
E13 8SL

Study participating centre
The Royal Free London NHS Foundation Trust
London

United Kingdom
NW3 2QG

Sponsor information

Organisation
University College London (UK)

Sponsor details
c/o Anne Marie Downey
Joint Research Office
1st Floor Maple House (Suite A)
149 Tottenham Court Road
London
England
United Kingdom
W1T 7DN

Sponsor type
University/education

Website
http://www.ucl.ac.uk/

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
Department of Health Policy Research Programme (UK) ref: 015/0306

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal within one year of end of study (by 30 /06/2018).

Intention to publish date

30/06/2018

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	21/01/2021	25/01/2021	Yes	No
HRA research summary			28/06/2023	No	No