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Chronic viral hepatitis in ethnic minorities

Submission date
21/01/2015

Registration date
22/01/2015

Last Edited
07/08/2019

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Digestive System

☐ Prospectively registered
☐ Protocol
☐ Statistical analysis plan
☒ Results
☐ Individual participant data

Plain English summary of protocol

Background and study aims
Hepatitis is the term used to describe inflammation of the liver, which can result from either a viral infection or exposure to a harmful substance (for example, alcohol). Chronic viral hepatitis is common in people born outside the UK and involves long-term infection with either the hepatitis B or C virus. The disease may not cause any symptoms but can, in time, lead to cirrhosis (scarring of the liver) or potentially hepatocellular carcinoma (a form of liver cancer) as well as death in a large proportion of those who are infected. Approximately 0.5% of the UK population is known to have viral hepatitis. However, it is believed that about 5% of first and second generation immigrants from at risk countries are affected. Current data relating to immigrant populations within the UK is limited. However, it is thought that 7 million first and second generation immigrants from countries where there is a high number of people with a hepatitis infection currently live in the UK. The UK has one of the lowest rates of therapy for viral hepatitis in Europe and this is undoubtedly contributing to the observed rising death rates from liver disease. This is in contrast to the rest of Europe, where mortality from liver disease is decreasing. This study looks at how to effectively identify and screen immigrants from ‘at risk’ ethnic minority communities as well as assessing the impact of primary care on engagement of targeted newly diagnosed chronic viral hepatitis patients.

Who can participate?
Adults aged at least 18 who are first generation immigrants born in a country at risk of viral hepatitis or second generation immigrants (as outlined by WHO classification of HBV prevalence >2%)

What does the study involve?
GP practices known be in an area where there are a high number of immigrant populations from ‘at risk’ countries are recruited. They are randomly allocated into one of three groups. Those in group 1 are control practices. Those in group 2 are in intervention group 1. Those in group 3 are in intervention group 2. In the GP practices in the interventional groups , existing GP registers of patients are screened to identify possible patients by recorded ethnicity, country of birth or their parents country of birth and first language spoken. Selected participants identified as first or second generation immigrants without HBV or HCV status, are then even contacted or approached to take part within the study. Patients are contacted either by letter, text message or when visiting the GP. Interventional practices are further randomised with half of the participants being sent a ‘standard’ invitation’ letter and the other half a 'augmented' invitation

letter. All those screened and tested positive for viral hepatitis are offered treatment in the specialist out patients clinic in their local hospital or in an intervention practice as part of community care. They are also monitored for their level of engagement as well as treatment compliance. Up to approximately 48,000 patients will be approached within the next 12-18 months. In the control group, existing GP registers of patients are screened to identify potential patients by their country of birth or their parents country of birth. A local hepatologist or a trained member of the study team also visit the GP practices, highlighting the study to the GPs and their teams and educating them about hepatitis B and C. These practices continue with their standard care policy relating to screening over the 12-18 months.

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

Where is the study run from?
Queen Mary University of London (UK)

When is the study starting and how long is it expected to run for?
February 2014 to June 2017

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Dr Stuart Flanagan

Contact information

Type(s)
Public

Contact name
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Scientific

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Additional identifiers

Protocol serial number
14034

Study information

Scientific Title
Chronic viral hepatitis in ethnic minorities: A controlled randomised cross sectional cluster trial to assess the impact of identifying, screening and treating immigrants with viral hepatitis

Acronym
HepFree

Study objectives
1. To assess the most cost effective method of screening for chronic viral hepatitis in primary care patients within at risk ethnic minority communities
2. To assess the impact of the interventional approach based strategy
3. To establish whether the involvement of community therapy is likely to have an impact on a patients engagement after having been positively tested for viral hepatitis
4. To assess differences in treatment compliance between patients groups receiving treatment within the community against those who have standard hospital care

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London-Fulham, 24/12/2012, ref: 12/LO/1768

Study design
A controlled randomised cross sectional cluster trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
The study will involve approaching/contacting approximately 48,000 males or females, first /second generation immigrants over the age of 18 from their GP practice to be screened for

Hepatitis B and C. Any participants that test positive for either Hepatitis B and/or C will either be referred as per standard care to their local hospital outpatients department or receive care within the community by the local specialist hepatology team at local 'interventional' practices.

Intervention Type
Mixed

Primary outcome(s)
1. The proportion of patients eligible to be screened (determined by a review of the number of immigrants registered at the GP practice at the initiation of the study)
2. The proportion of potential patients that attend for testing
3. The proportion of potential patients that engage in therapy (defined as attending on at least 3 different occasions) in the different treatment arms

Key secondary outcome(s))
Compliance will be measured upon 80% completion of prescribed therapy, as confirmed at 12 month follow

Completion date
30/06/2017

Eligibility

Key inclusion criteria
1. Patients of either gender who have been identified as first generation immigrants born in a country of high risk or second generation immigrants (as outlined by WHO classification of HBV prevalence >2%)
2. At least 18 years of age

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Participants that are lacking capacity

Date of first enrolment
06/02/2014

Date of final enrolment
31/03/2016

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Queen Mary University of London
Wolfson Institute of Preventative Medicine
Charterhouse Square
London
United Kingdom
EC1M 6BQ

Sponsor information

Organisation
Queen Mary, University of London

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype

National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be included in the subsequent results publication.

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	01/01/2019		Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes