Screening for viral hepatitis in migrants in East London

Submission date	Recruitment status Stopped	Prospectively registered		
25/10/2013		☐ Protocol		
Registration date	Overall study status Stopped	Statistical analysis plan		
25/10/2013		Results		
Last Edited	Condition category Infections and Infestations	Individual participant data		
07/08/2019		☐ Record updated in last year		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

14808

Study information

Scientific Title

Screening for viral hepatitis in migrants in East London: a pilot study of the HEPscreen project comparing screening invitation with and without HIV testing

Acronym

HEPscreen

Study objectives

The aim of this study is to determine any difference in the number of candidates attending for testing in primary health care facilities when offered testing for viral hepatitis with or without concomitant testing for HIV.

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Committee London - Brent, 08/04/2013, ref: 13/LO/0215

Study design

Randomised interventional screening trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Screening

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

Screening for viral hepatitis

Interventions

Screening, Addition of invitation for HIV testing to testing for viral hepatitis.

The participants will be sent a letter inviting them to come to their GP practice for a questionnaire and a blood test. The difference between the two arms is the text in the invitation letter. The visit to the practice is a one-stop appointment and follow-up is determined by the test results and will take place in the way of usual clinical care. The primary outcome is the number of participants that attend for testing in each arm.

Follow Up Length: 12 months

Study Entry: Single Randomisation only

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Number of participants responding to invitation letter; Timepoint(s): 31/03/2013

Secondary outcome measures

- 1. To determine the prevalence of viral hepatitis in different migrant populations when approached for testing in primary health care facilities.
- 2. To determine the number of persons infected with hepatitis B or C who then proceed on to secondary, tertiary health care and treatment, respectively.

These secondary outcomes will be measured at the end of the study.

Overall study start date

15/08/2013

Completion date

31/03/2014

Reason abandoned (if study stopped)

Participant recruitment issue

Eligibility

Key inclusion criteria

- 1. Migrants (i.e. person or parents born outside the UK in high or intermediate Hepatitis B and C prevalence countries)
- 2. Male & female, 18 years and older
- 3. Registered with primary care practices in East London

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

UK Sample Size: 500; Description: 500 people to be invited for testing. The study takes place in the London Borough of Hackney in Primary Care.

Key exclusion criteria

- 1. Withheld consent
- 2. Age < 18 years
- 3. Previously known infection with HBV, HCV or HIV or previous test
- 4. Lacking capacity

Date of first enrolment

15/08/2013

Date of final enrolment

31/03/2014

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Centre for Digestive Diseases

London United Kingdom E1 2AT

Sponsor information

Organisation

Queen Mary University of London (UK)

Sponsor details

Centre for Digestive Diseases Blizard Institute London England United Kingdom E1 2AD

Sponsor type

University/education

Website

http://www.qmul.ac.uk/

ROR

https://ror.org/026zzn846

Funder(s)

Funder type

Government

Funder Name

EU Commission Framework 7; Grant Codes: 20101105

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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?
HRA research summary			28/06/2023	No	No