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Screening for viral hepatitis in migrants in East London

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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
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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