ISRCTN17873610 https://doi.org/10.1186/ISRCTN17873610

Viral hepatitis case-finding in primary care

Submission date
09/10/2014

Recruitment status
No longer recruiting

Registration date
09/10/2014

Overall study status
Completed

Last Edited
25/06/2020

Condition category
Haematological Disorders

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

Plain English summary of protocol

Background and study aims
Hepatitis B and C are blood-borne viruses that affect the liver. Long-term (chronic) infection with hepatitis B or C (HBV and HCV) is the leading cause of end-stage liver disease (cirrhosis) and primary liver cancer worldwide. In the UK, the rates of hospital admissions and serious complications due to hepatitis C (HCV) continues to rise year on year, with HCV now being the leading cause of liver transplantation in Europe and North America. Chronic infection with HBV and HCV seems more common in certain groups of people (at-risk groups), and due to several risk factors. Case-finding is the process by which at-risk individuals are identified and offered testing for viral hepatitis. As chronic infection typically causes few symptoms, it is important that those at-risk are offered testing to identify the virus early. Good effective treatment exists for both HBV and HCV, with several new treatments for hepatitis C released in the past year. Identification and treatment will eliminate or reduce the chances of disease progression, and this is the goal of case-finding. National and international guidance exists to support case-finding and insists on identifying those groups who should be offered testing for HBV and HCV in England. A key target of these recommendations is to increase testing in GP practices. As the majority of those infected with viral hepatitis lie in the community, offering testing to people in GP practices is priority. There is however no recommended strategy, and little research to guide GPs on how best to identify and offer testing to at-risk individuals in their practice. At the same time, most GP practices are finding it difficult to meet the existing service commitments, with no additional resources provided for case-finding. Developing and proving effective and acceptable case-finding strategies in GP practices is therefore a priority.

Who can participate?
GP practices with suitable computer recording software and those with links to hepatology speciality services.

What does the study involve?
In this study we will look at 3 different testing strategies for GP practices to identify and offer testing to individuals with increased risk of viral hepatitis, in comparison to current practice. GPs will be asked to identify and offer testing for viral hepatitis to their patients in one of three ways: systematic, opportunistic or new-patient testing, in comparison to a group of (control) GP practices undertaking usual testing practice. At-risk groups will be identified. In the Systematic arm of the study, we will identify at-risk groups within the GP practice, and write to offer them HBV and HCV testing. In the Opportunistic arm of the study, GPs will offer testing to at-risk

individuals who present to their GP for related, or unrelated consultations, and in the New-patient arm of the study, new patient registrations will be asked additional questions to identify risk factors that would merit a testing offer for HBV or HCV. Testing is optional, and we will record the uptake of testing in each arm, in comparison to testing uptake in the control GP practices.

What are the benefits and risks of participating?
The main benefit of the study is to help improve the detection of those infected with viral hepatitis, with the aim of treatment before complications arise. The study will also help improve our understanding of the number of at-risk individuals in GP practices, and in this population the actual numbers infected with viral hepatitis. We do not expect any undue risks for participants by taking part in this study. Testing will be at their wish, and participants will be given the opportunity for further discussions if they so wish before testing.

Where is the study run from?
The study will be conducted in local GP practices.

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

Who is funding the study?
Gilead Sciences Inc (USA)

Who is the main contact?
Dr Sanju Mathew
s.mathew@surrey.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Sanju Mathew

Contact details
Faculty of Health and Medical Science
Guildford
United Kingdom
GU2 7XH
--
s.mathew@surrey.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
17297

Study information

Scientific Title
A feasibility study of case-finding strategies for the detection of Hepatitis B and C in primary care

Study objectives
National and international guidance recommends offering testing for hepatitis B and C to at-risk groups (case-finding). Identifying these individuals in primary care is a priority, with the majority of those infected known to remain undetected in the community. There is however little research to guide effective case-finding practice in primary care, with this taking a low priority in many practices.
In the following feasibility study we will prospectively assess three case-finding strategies in primary care, in comparison to standard (usual) practice. Through this we aim to develop and prove effective case-finding strategies for viral hepatitis (B &C) that can be adopted in primary care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
14/EE/1159; First MREC approval date 25/09/2014

Study design
Non-randomised; Interventional and Observational; Design type: Screening, Qualitative

Primary study design
Interventional

Secondary study design
Non 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
Topic: Primary Care; Subtopic: Hepatology, Primary care; Disease: All Diseases

Interventions
New-patient testing: New patient registrations will be asked additional questions relating to HBV and HCV risks.

Testing will be offered based on risk.
Opportunistic testing, At-risk patients will be offered HBV and HCV testing when presenting to GP practices for related/unrelated reasons
Systematic testing, GP practices will identify at-risk groups in their patient population using MIQUEST coding. Written invites will be sent to patients to offer HBV and HCV testing
Follow Up Length: 3 month(s); Study Entry : Other; Details: Practices will be recruited with the help of the PCRN team

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Uptake of testing for Hepatitis B / C; Timepoint(s): The uptake of testing in intervention arms compared to control
(usual care). Over 3 months

Secondary outcome measures
1. Acceptability of testing intevention; Timepoint(s): at end of testing period (3 months)
2. Positive cases for HBV and HCV; Timepoint(s): Over 3 months

Overall study start date
10/11/2014

Completion date
16/02/2015

Eligibility

Key inclusion criteria
1. Practices will be selected with appropriate and eligible computer recording software
2. Practices with links to hepatology speciality services to provide support and onward referral
3. Practices with resource abilities to offer testing strategies

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 540; UK Sample Size: 540

Key exclusion criteria

1. Practices without adequate computer records software
2. Practices without computer-linked results recording to laboratory services

Date of first enrolment
10/11/2014

Date of final enrolment
16/02/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Faculty of Health and Medical Science
Guildford
United Kingdom
GU2 7XH

Sponsor information

Organisation
University of Surrey (UK)

Sponsor details
Faculty of Health and Medical Science
Guildford
England
United Kingdom
GU2 7XH

Sponsor type
University/education

ROR
https://ror.org/00ks66431

Funder(s)

Funder type

Industry

Funder Name
Gilead Sciences Inc (USA) - Grant Codes: 999/UK/13-05/CI/1010

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