

Hepatitis C assessment to treatment trial

Submission date 22/04/2015	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 24/04/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 10/03/2020	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Hepatitis C is a virus that can infect the liver. Most people do not have any symptoms as they do not arise until the virus has caused significant damage to the liver. When they do occur, they tend to be vague and similar to a number of other conditions. They include flu-like symptoms, feeling tired and depression. People can get infected with the virus if they come into contact with the blood of an infected person, for example, by sharing drug needles. Due to the condition not having any obvious symptoms, regular testing is recommended for people considered to be in a high risk group, for example drug users. Here, we want to see if we can increase testing and diagnosis of people at an increased risk of hepatitis C virus (HCV) infection in the primary care setting (for example, at GP surgeries).

Who can participate?

Patients that have been approached by their GPs for HCV testing and attending a participating GP practice.

What does the study involve?

Participating GP practices are randomly allocated into one of two groups. Those in group one are given a complex intervention (or programme) consisting mainly of targeted case finding and inviting high risk patients to the practice for a test. Those in group two are not given the intervention and carry on as usual. We also look at how acceptable both patients and health care providers find the intervention and identify potential modifications that may be required to encourage HCV testing in primary care. At the end of the study we compare HCV testing, diagnosis, assessment and treatment rates between intervention and control sites. If the interventions are acceptable, work well and cost-effective then we will encourage their roll-out in primary care.

What are the possible benefits and risks of participating?

Some high-risk HCV patients registered at the intervention practices may be given an earlier test or diagnosis as a result of the practice being involved in the study. For the participants involved in the qualitative study, although there may not be any direct benefit from taking part, they will be helping to improve future services and treatment accessibility for people living with HCV. We do not foresee any potential risks to the patients. For the qualitative interviews, the only risk we foresee is related to patient inconvenience related to consent procedures and participation in the interviews.

Where is the study run from?

Primary care practices in the South West of England (UK)

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

June 2015 to December 2017

Who is funding the study?

Department of Health - National Specialised Commissioning Team (UK)

Who is the main contact?

Dr Kirsty Roberts

Contact information

Type(s)

Scientific

Contact name

Dr Kirsty Roberts

Contact details

School of Social and Community Medicine

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Additional identifiers

Protocol serial number

18696

Study information

Scientific Title

Evaluation of interventions designed to increase diagnosis and treatment of patients with Hepatitis C virus infection in primary care

Acronym

HepCATT

Study objectives

This study will determine whether we can increase testing and diagnosis of individuals at increased risk of HCV infection in primary care with a complex intervention consisting mainly of targeted case finding and inviting high risk patients to the practice for a test. We will also conduct a nested qualitative study with patients and health-care providers to assess the acceptability of the intervention and identify potential modifications that may be required to encourage HCV testing in primary care.

Ethics approval required

Old ethics approval format

Ethics approval(s)

15/SW/0094

Study design

Randomised; Interventional and Observational; Design type: Diagnosis, Screening, Qualitative

Primary study design

Interventional

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Topic: Primary Care; Subtopic: Primary care; Disease: All Diseases

Interventions

HCV test algorithm: The HCV test algorithm will run a search on GP systems to generate a list of individuals with risk markers for HCV infection

1. Increasing patient awareness, displaying Hepatitis C posters and leaflets in the practice waiting rooms
2. Increasing practice awareness
3. An offer of educational training on HCV for practice staff

Intervention Type

Other

Primary outcome(s)

Number/proportion of patients tested for HCV; Timepoint(s): 12 months

Key secondary outcome(s)

1. Cost of case finding and testing; Timepoint(s): 12 months
2. Incremental cost per case detected; Timepoint(s): 12 months
3. Number and proportion testing positive (yield); Timepoint(s): 12 months
4. Number/ proportion attending for assessment; Timepoint(s): 12 months
5. Number/ proportion initiating treatment; Timepoint(s): 12 months
6. Number/ proportion referred for specialist assessment; Timepoint(s): 12 months

Completion date

31/12/2017

Eligibility

Key inclusion criteria

For patient interviews:

1. Individuals approached by their GP for a HCV test in participating intervention practices who are aged over 18 years old
2. Able to provide informed consent and who have a telephone they can be contacted on

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

For the patient interviews:
Unable to provide informed consent

Date of first enrolment

01/06/2015

Date of final enrolment

31/12/2016

Locations**Countries of recruitment**

United Kingdom

Study participating centre**Bristol Primary Care Trust (lead)**

Bristol

United Kingdom

-

Study participating centre**North Somerset Primary Care Trust**

Somerset

United Kingdom

-

Study participating centre

South Gloucestershire Primary Care Trust

Gloucestershire

United Kingdom

-

Sponsor information

Organisation

University of Bristol (UK)

ROR

<https://ror.org/0524sp257>

Funder(s)

Funder type

Government

Funder Name

Department of Health - National Specialised Commissioning Team; Grant Codes: 015/0309

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Prof. Matthew Hickman (matthew.hickman@bristol.ac.uk), the CI for HepCATT and the data controller. Access to this data will be available shortly. The anonymised data set will be stored in the research data facility at the University of Bristol.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	30/07/2020	26/02/2020	Yes	No
Results article	cost-effectiveness results	26/02/2020	10/03/2020	Yes	No
Protocol article	protocol	29/07/2016		Yes	No
HRA research summary			28/06/2023	No	No