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Hepatitis C assessment to treatment trial

Submission date
22/04/2015

Recruitment status
No longer recruiting

Registration date
24/04/2015

Overall study status
Completed

Last Edited
10/03/2020

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

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

Secondary outcome measures

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

Overall study start date
01/07/2014

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 920; UK Sample Size: 920

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)

Sponsor details
Department of Social Medicine
Canynge Hall
Whiteladies Road
Bristol
England
United Kingdom
BS8 2PR

Sponsor type
University/education

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

Publication and dissemination plan
We plan to publish the results of the trial in a peer-reviewed journal and at national conferences.

Intention to publish date
01/07/2019

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?
Protocol article	protocol	29/07/2016		Yes	No
Results article	results	30/07/2020	26/02/2020	Yes	No
Results article	cost-effectiveness results	26/02/2020	10/03/2020	Yes	No
HRA research summary			28/06/2023	No	No