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Addressing low treatment rates of chronic hepatitis C in injecting drug users

Submission date
10/04/2012

Recruitment status
No longer recruiting

Registration date
19/06/2014

Overall study status
Completed

Last Edited
07/03/2017

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Chronic hepatitis C virus (HCV) is a virus that infects the liver and can lead to liver cirrhosis and cancer. In the United Kingdom the majority of people infected with hepatitis C got the virus as a result of injecting drugs with infected needles , but less than 10% of people with HCV in this group have been treated despite the fact that with treatment most people can be cured. To address this in North East London an outreach treatment service was set up in 2004 whereby a team of experienced nurses that specialise in blood borne viruses provide HCV treatment for injecting drug users in community clinics based in Specialist Addiction units, drug and alcohol charities, hostels for the homeless and a GP practice for the homeless. This has increased treatment rates locally to approximately 17% but this could still be improved. The aim of this study is to explore the reasons behind the low uptake of antiviral therapy for HCV in injecting drug users and to trial a novel way of delivering treatment with the aim of increasing the proportion of injecting drug users who start and complete treatment for hepatitis C.

Who can participate?
Participants are injecting drug users who have been diagnosed with hepatitis C virus and are under the care of Specialist Addiction Services in the Hackney, Tower Hamlets and Newham boroughs of London.

What does the study involve?
The study involves three separate parts:
Part 1 will involve qualitative semi-structured research interviews with injecting drug users with HCV and focus groups of healthcare professionals involved in the treatment of injecting drug users with HCV.
Part 2 is a retrospective audit, reviewing and evaluating the treatment and social outcomes of injecting drug users who have received antiviral therapy for HCV within the Blood borne virus nursing outreach service
Part 3 is an initial (pilot) study comparing outcomes of nurse led prescribing of antiviral therapy for HCV with doctor led prescribing in blood borne virus team outreach clinics. This will involve patients being randomised to nurse initiated or doctor initiated antiviral therapy for HCV dependent on which outreach clinic they attend. The nurse led clinics will have a strict protocol ensuring that only low risk patients (as defined by previous medical and psychiatric history) can

be treated by nurses. Patients who are not eligible for nurse led treatment will be referred for doctor led treatment which is the current standard of care.

What are the possible benefits and risks of participating?
The possible benefits of participating in the study for participants treated by the nurses are that they will be offered treatment at an earlier stage and in a more convenient environment to them. We hope this will increase the likelihood of them starting and completing treatment, and of being cured of hepatitis C. Participants who have taken part in the research interviews may gain a benefit as their answers will enable us to gain a greater understanding of the reasons for the low uptake of therapy which may lead to redesign of services to better suit their needs. Potential risks for participants may occur in the interviews and during the trial. During the interviews questions asked about living with hepatitis C virus infection and treatment may be upsetting. During the trial blood tests will be performed which could be mildly uncomfortable and participants will be warned about this. There will be patients who are at higher risk of side effects from treatment for hepatitis C where the decision to start treatment should not be made in a nurse led clinic. The protocol will ensure that all these patients are excluded from nurse led treatment. They will be referred to the hepatology outreach clinic, as presently occurs.

Where is the study run from?
East London NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
April 2011 to April 2013

Who is funding the study?
Roche Pharmaceuticals (UK)

Who is the main contact?
Dr Heather Lewis
heatherilewis@hotmail.com

Contact information

Type(s)
Scientific

Contact name
Prof Graham Foster

Contact details
Blizzard Institute for Cell and Molecular Science
Queen Mary University of London
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E11 2EZ

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2

Study information

Scientific Title
Addressing low treatment rates of chronic hepatitis C in injecting drug users: Why do injecting drug users not engage in treatment, what are the health and social benefits for those who do engage in treatment, and does nurse led initiation of antiviral therapy increase the proportion accepting and completing treatment?

Study objectives
A system of nurse initiated antiviral therapy for injecting drug users with hepatitis C virus will result in greater numbers of patients starting and completing antiviral therapy, and being cured of hepatitis C virus than a doctor initiated system.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Research Ethics Committee Service City Road and Hampstead, 09/06/2011, ref: 11/LO/0347

Study design
Part 1: Qualitative semi-structured research interviews and focus groups
Part 2: Retrospective audit
Part 3: Prospective randomised trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied

Hepatitis C virus treatment

Interventions
Nurse-led initiation of standard antiviral therapy for hepatitis C virus in nurse-led outreach clinics

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Number of patients who achieve a sustained viral response
2. Number of patients who are compliant with treatment
3. Number of patients who start and finish treatment

Secondary outcome measures
Change in alcohol and drug use of participants

Overall study start date
01/04/2011

Completion date
01/04/2013

Eligibility

Key inclusion criteria
1. Hepatitis C virus (HCV) positive (as shown by a positive HCV RNA level)
2. Attending Specialist Addiction Services in the boroughs of Hackney, Newham or Tower Hamlets in London

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
402

Key exclusion criteria
1. A negative test for HCV infection
2. People who are not registered with specialist addiction services
3. Those who have evidence of any of the following:
4. Cirrhosis of the liver - blood test, imaging or liver biopsy evidence
5. Anaemia (low red cells) Haemoglobin <12

6. Thrombocytopenia (low platelet count) <150
7. Lymphopenia (low white cells) < 3
8. Active infection of any kind
9. Serious psychiatric disorders in the last two years
4. Uncontrolled asthma
5. Chronic obstructive pulmonary disease
6. Ischaemic heart disease, or severe cardiac disease including ventricular arrhythmias, angina and heart failure, renal failure, autoimmune disease

Date of first enrolment
01/04/2011

Date of final enrolment
01/04/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Queen Mary University of London
London
United Kingdom
E11 2EZ

Sponsor information

Organisation
Barts and the London NHS Trust (UK)

Sponsor details
Joint Research and Development Office
Queen Mary Innovation Centre
5 Walden Street
Whitechapel
London
England
United Kingdom
E11 2EZ

Sponsor type
Hospital/treatment centre

Website
http://www.bartsandthelondon.nhs.uk/

ROR
https://ror.org/00b31g692

Funder(s)

Funder type
Industry

Funder Name
Roche Pharmaceuticals (UK)

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?
Results article	results	01/11/2016		Yes	No