ISRCTN72038467 https://doi.org/10.1186/ISRCTN72038467

What is the impact of antiviral treatment for people who inject drugs on the overall number of new hepatitis C infections within the population of injecting drug users?

Submission date
19/12/2018

Recruitment status
No longer recruiting

Registration date
24/01/2019

Overall study status
Completed

Last Edited
20/09/2023

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
An estimated 200,000 people in the UK have been infected with the Hepatitis C Virus (HCV), which is an important cause of liver disease, cancer and death. Most HCV infections in the UK are in people who inject drugs. New HCV drugs cure over 90% of patients within 12 weeks with few side-effects, but are expensive (over £20,000) and currently restricted to people with moderate or severe liver disease.

Mathematical models suggest that HCV "Treatment as Prevention", i.e. treating people who inject drugs and have mild liver disease for HCV, can reduce the overall number of new HCV infections in the population, even though some people who inject drugs may also become re-infected. Further, if HCV treatment is increased sufficiently, then HCV will eventually be "eliminated" from the UK population. However, the findings from these models need to be tested out in patients. – This is what we aim to address.

Who can participate?
WS1 and 3: People who are injecting drug users, who have had a diagnosis of HCV are eligible to participate. They must be over the age of 18 years old, able to consent (for example, not intoxicated by alcohol) and not have any mental health or behavioural problems which would affect their participation.

What does the study involve?
WS1: Quantitative: completion of a short questionnaire containing questions on living circumstances and drug use. There are also five questions about how healthy participants feel. The completion of these questionnaires will be completed at the start of treatment, completion of treatment, 12 weeks post treatment and one-year post treatment.

WS3: Qualitative:
Treatment completers: A one-to-one interview with either a peer or academic researcher after completion of treatment.

Treatment refusers: A one-to-one interview with either a peer or academic researcher after refusal of treatment.

Staff: Focus groups, facilitated by academic staff, in the latter stages of up-scaling treatment.

What are the possible benefits and risks of participating?
The study may not benefit participants directly, but it is hoped that the results will help improved the treatment of Hepatitis C within the PWID population.

WS1: Quantitative: There are no anticipated risks associated with completing the short questionnaires. Any side effects of the medication or tests undertaken will be explained fully by the doctor, nurse or pharmacist involved the care of participants, but these are standard risks that are not associated solely with this study.

WS3: Qualitative: Participants may find that talking about their experiences upsetting. If this happens, they will be able to take a break from the interview, after which the researcher will ask if they are prepared to continue. If additional support is required, the researcher can arrange for them to speak to one of the service staff in addition to offering a list of local services that may help.

Where is the study run from?
The research programme is being coordinated in Bristol, with researchers across Scotland and England collaborating on each of the work streams.

Participants for WS1 and 3 are being recruited in Dundee. WS1 is being coordinated from Dundee and WS3 from Glasgow.

When is the study starting and how long is it expected to run for?
The grant started in February 2018. Recruitment and follow-up will continue for two years. WS1-4 will all feed into inform the protocol for WS5, which is scheduled to be completed in 2020.

The programme of research will be completed in 2023.

Who is funding the study?
The study is funded by NIHR.

Who is the main contact?
Jade Meadows, jade.meadows@bristol.ac.uk

Study website
https://www.bristol.ac.uk/population-health-sciences/projects/epitope/

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
WS 1 and 3: Sponsor: 1-005-18, R&D:2016GA10

Study information

Scientific Title
Evaluating the Population Impact of hepatitis C direct-acting antiviral Treatment as Prevention for people who inject drugs: a non-randomised trial

Acronym
EPIToPe

Study objectives
HCV Treatment scale-up for PWID, and resulting HCV Treatment as Prevention (TasP) could enhance other primary interventions and reduce HCV incidence and chronic prevalence to negligible levels (i.e. towards elimination as a major public health concern)

Ethics approval required
Old ethics approval format

Ethics approval(s)
East of Scotland REC 1, 20/11/2018, ref. 18/ES/0128.

Study design
Interventional non-randomised study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Community

Study type(s)
Other

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

Health condition(s) or problem(s) studied
Hepatitis C

Interventions
Work stream (WS) 1: the removal of any restrictions of access to treatment by disease stage and scaling-up treatment in PWID. Treatment of hepatitis C (HCV) will be offered to active drug users across 4 novel treatment pathways: pharmacy, needle exchange services, prisons and drug treatment centres. Participants will be recruited over a one-year period. Participants will be followed up at 12 weeks and one-year post treatment. In addition, to the novel pathways being offered, an up-scale of the numbers being offered treatment is also planned.

WS 5: an increase in HCV treatment for PWID with mild disease as with WS1.

Intervention Type
Other

Primary outcome measure
The utility status of HCV infection and the change in utility with treatment and cure will be measured using the EQ5D5L questionnaire at treatment start, treatment end, 12 weeks following end of treatment and one year following treatment.

Secondary outcome measures
1. The experiences and perceptions of service providers will be measured using qualitative interviews and/or focus groups during the latter stages of treatment scale -up during 2018-2019.
2. The experiences and perceptions of individuals undergoing HCV treatment will be measured using qualitative interviews post treatment and around one year later.
3. The experiences and perceptions of individuals refusing HCV treatment will be measured using qualitative interviews once following refusal of treatment.

Overall study start date
01/02/2018

Completion date
31/07/2024

Eligibility

Key inclusion criteria
1. HCV diagnosis
2. Injecting drug use
3. Aged 18 years or over

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
WS1 and 3 : 500

Total final enrolment
555

Key exclusion criteria
1. Mental health or behavioural problems e.g. psychosis, aggressiveness.

Date of first enrolment
15/01/2019

Date of final enrolment
30/04/2021

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
NHS Tayside
NHS Tayside
Address Kings Croos
Clepington Road
Dundee
DD3 8EA
SCOTLAND

Dundee
United Kingdom
DD3 8EA

Sponsor information

Organisation
University of Dundee

Sponsor details
TASC, Residency Block
Level 3, Ninewells Hospital
Dundee
Scotland
United Kingdom
DD1 9SY

Sponsor type
University/education

ROR
https://ror.org/03h2bxq36

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan

Month - Paper
12 Paper_3: Trial methods
18 Draft Paper_8: Chronic HCV 2010-2016
18 Paper_14: Providers perspectives
24 Draft Paper_4: Can rapid scale-up be achieved
24 Draft Paper_7: Health utilities
24 Draft Paper_9: Chronic HCV 2010-2019/20
24 Draft Paper_15: Patient perspectives on TasP
30 Dissemination Event & Draft Paper_18: Manual
33 Draft Paper_27: Progress report
33 Draft Paper_27: Protocol
48 Draft Paper_6: Re-infection rates
56 Draft Paper_13: Addiction outcomes of HCV SVR vs untreated PWID
60 Paper_28: Qualitative insights
60 Paper_29: Evaluation outcomes
60 Paper_30: Cost-effectiveness

Intention to publish date

31/08/2024

Individual participant data (IPD) sharing plan

Our aim is to store data in a publicly available repository, however plans will have to be made for the qualitative and linked data. The data sharing plans for the current study will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		24/09/2019	15/09/2021	Yes	No
HRA research summary			20/09/2023	No	No