

# 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?

<b>Submission date</b> 19/12/2018	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 24/01/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 11/02/2026	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data

## 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

## Contact information

**Type(s)**

Public

**Contact name**

Mrs Beth Thorne

## Contact details

Population Health Sciences  
Bristol Medical School  
Oakfield House (OF22)  
Bristol  
United Kingdom  
BS8 2BN  
+44 (0)117 331 3320  
beth.thorne@bristol.ac.uk

## Additional identifiers

### Protocol serial number

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

### Study type(s)

Other

### 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(s)**

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.

## **Key secondary outcome(s)**

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.

## **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

## **Healthy volunteers allowed**

No

## **Age group**

Mixed

## **Lower age limit**

18 years

## **Upper age limit**

120 years

## **Sex**

All

**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**

United Kingdom

Scotland

**Study participating centre****NHS Tayside**

NHS Tayside

Address Kings Croos

Cleington Road

Dundee

DD3 8EA

SCOTLAND

Dundee

Scotland

DD3 8EA

**Sponsor information****Organisation**

University of Dundee

**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

**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**

Stored in publicly available repository

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		08/12/2021	11/02/2026	Yes	No
<a href="#">Protocol article</a>		24/09/2019	15/09/2021	Yes	No
<a href="#">HRA research summary</a>			20/09/2023	No	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes