Submit your Final Report

Your Submission

Name of Chief Investigator

Professor John F Dillon

Telephone Number of Chief Investigator

01382383017

Email address of Chief Investigator

j.f.dillon@dundee.ac.uk

Chief Investigator ORCID ID

0000-0002-2164-4476

Full Study Title

A Direct obserVed therApy vs fortNightly CollEction Study for HCV Treatment – ADVANCE HCV Study

IRAS ID

225727

Name of the Research Ethics Committee that issued a Favourable Opinion for the study

East of Scotland Research Ethics Service REC 1

Sponsor Organisation Name

University of Dundee/NHS Tayside

Study start date

2018-01-19

Study end date

2020-10-28

Funder's reference number

MISP 53605 ADVANCE HCV

Name of Registry

clinicaltrials.gov

Study Registration Number/Identifier

NCT03236506

Date of registration

04/07/2017

Is the study protocol publicly available?

Yes

DOI/URL for most recent protocol

https://doi.org/10.1136/bmjopen-2019-029516

Date original protocol was published

2019-08-08

Lay summary of study results

Analysis was performed on 110 participants who completed the study to identify differences in sustained viral response to hepatitis c infection 12 weeks post treatment (SVR12) between the three treatment regimes. 33 participants received daily observed therapy, with 90.91% SVR12; 37 received fortnightly provision, with 86.49% SVR12 and 40 received fortnightly provision and psychological intervention at treatment initiation, with 92,50% SVR12. Analysis showed no significant statistical difference in SVR12 rate (p= 0.67).

Has the registry been updated to include summary results?

Yes

If yes - please enter the URL to summary results

https://clinicaltrials.gov/ct2/show/record/NCT03236506?term=NCT03236506&cond=Hepatitis+C&draw=2&rank=1

Did you follow your dissemination plan submitted in the

Did you follow your dissemination plan submitted in the IRAS application form (Q A51)?

Pending

If pending, date when dissemination is expected

2022-01-03

Have participants been informed of the results of the study?

Yes

If yes, describe and/or provide URLs to materials shared and how they were shared

A leaflet containing a lay summary of the study results was made available at the two recruiting sites and passed to all participants who were still in regular contact at the sites, and was free to read for any other interested persons.

Have you enabled sharing of study data with others?

Yes

If yes, describe or provide URLs to how it has been shared

Data can be made available for sharing on request and in published form when available.

Have you enabled sharing of tissue samples and associated data with others?

Yes

If yes, describe or provide a URL

Blood samples taken have been made available to the local biorepository. Some of these samples will be analysed by local toxicology and compared to a similar patient group.

Planning and improving research

Research planning

Best Practice

Policies, Standards & Legislation

Learning

Confidentiality Advisory Group registers

Research summaries

Approvals and amendments

What approvals and decisions do I need?

Amending an approval

Managing your approval

About the HRA

What we do

Who we are

Committees and services

Consultations

Partnerships

Governance

News & updates

HRA Latest

Vacancies

Glossary

Research Ethics Committees

RECs and RECs

Search for a REC

REC Standard Operating Procedures

REC members' area

Become a REC member

Follow us

Health Research Authority
2 Redman Place,
Stratford, London,
E20 1JQ

Contact us Privacy notice

Terms & conditions

Accessibility statement for HRA website

Feedback or concerns

Site by Big Blue Door

We need your feedback! We are still testing the new HRA website to ensure it meets your needs. Please complete our short feedback form.