

WORKING TOWARDS MICRO-ELIMINATION OF HCV IN PWID. A DIRECT OBSERVED THERAPY VS FORTNIGHTLY COLLECTION STUDY FOR HCV TREATMENT – ADVANCE HCV STUDY

Sharkey C¹, Robinson EM^{1,2}, Ahmad F¹, Beer L³, Byrne C³, Inglis SK³, Johnson L², Nelson Y¹, Malaguti A⁴, Qumsieh J¹, Stephens BP¹, Dillon JF^{1,2}

¹Ninewells Hospital and Medical School, NHS Tayside. ²Department of Molecular and Clinical Medicine, University of Dundee. ³Tayside Clinical Trials Unit, University of Dundee.

⁴Adult Psychological Therapies Service, NHS Tayside.

Background: Direct Acting Antivirals (DAA) are now the standard of care for HCV treatment and shown to be efficacious in populations of people who inject drugs (PWID).

Achieving elimination depends on all affected people being treated and on convincing payors that treatment is expedient for services reaching clients with unresolved intravenous opiate dependency, alongside multifarious co-morbidities.

Targeted, multi-stakeholder interventions are needed to micro-eliminate HCV among PWID populations in order to achieve HCV elimination targets.

Methods: ADVANCE is a 2-year randomised, un-blinded trial which explores feasibility and efficacy of treating PWID by nurses embedded within injecting equipment provision sites (IEPS), without requirement to engage in opiate substitution therapy programmes.

PWID with chronic HCV (genotype 1 & 3) are randomised to one of three dispensing regimes; 'daily observed treatment' (DOT), 'fortnightly dispensed' (FD) and 'fortnightly dispensed with a psychological intervention for adherence' (FDPI).

Genotype 1 receive twelve weeks elbasvir/grazoprevir and Genotype 3 eight weeks of elbasvir/grazoprevir plus sofosbuvir.

The primary outcome is comparison of sustained viral response (SVR12) from each group.

Secondary analyses include adherence, reinfection rates, viral resistance to treatment and interaction of therapy with illicit drugs.

Results: Since February 2018, 91 participants have enrolled, with 87% established on HCV treatment (25 DOT, 31 FD, 28 FDPI).

58/90 (64%) participants are male and 52 (57%) are Genotype 3.

At present the trial has an SVR12 rate of 92% in those who have been tested (33/36).

Conclusion: Utilisation of community pathways and strategies to improve treatment uptake and adherence will be vital to treat, cure and micro-eliminate HCV in this population.

High engagement rate in this trial demonstrates treating active PWID via nurses embedded within IEP's is acceptable and viable.

The SVR12 rate to date suggests micro-elimination of HCV in this context is plausible. The final trial results can inform this further.

Disclosure of Interest Statement: This study is an Investigator initiated study funded by Merck Sharp & Dohme.

Elbasvir/grazoprevir was provided gratis by Merck Sharp & Dohme as 'zepatier'.

CS, EMR, FA, LB, CB, SKI, LJ, YN, AM, JQ, declare no conflict of interest.

BPS has honoraria for lectures from Janssen-Cilag, Merck Sharp & Dohme and Gilead Sciences.

JFD has honoraria for lectures and research grants from Janssen-Cilag, Roche, Merck Sharp & Dohme, AbbVie, Bristol-Myers Squibb, & Gilead.