

OPPORTUNISTIC TREATMENT OF HEPATITIS C VIRUS INFECTION (OPPORTUNI-C): STUDY PROTOCOL FOR A PRAGMATIC STEPPED WEDGE CLUSTER RANDOMIZED TRIAL OF IMMEDIATE VERSUS OUTPATIENT TREATMENT INITIATION AMONG HOSPITALIZED PEOPLE WHO INJECT DRUGS

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Background:

Hospitalizations may represent opportunities to engage marginalized people who inject drugs (PWID) in HCV care. This abstract presents the protocol for an ongoing trial of immediate versus outpatient HCV treatment initiation among hospitalized PWID (ClinicalTrials.gov, NCT04220645).

Methods:

OPPORTUNI-C is a pragmatic stepped wedge cluster randomized trial comparing the efficacy of immediate HCV treatment with the current standard of care among PWID admitted for inpatient care. The intervention includes non-invasive liver disease assessment and immediate initiation of pan-genotypic DAA treatment with individualized follow-up. Standard of care is a referral to outpatient care at discharge. To mimic usual clinical practice as closely as possible, we will use a pragmatic clinical trial approach utilizing clinical infrastructure, broad eligibility criteria, flexible intervention delivery, clinically relevant outcomes, and collection of data from the electronic patient files. The stepped wedge design involves a sequential rollout of the intervention, in which seven participating clusters will be randomized from standard of care to intervention in a stepwise manner (Figure). The trial will include approximately 220 HCV RNA positive individuals recruited from departments of internal medicine, addiction medicine, and psychiatry at three hospitals in Oslo, Norway. The primary outcome is treatment completion, defined as dispensing of the final prescribed DAA package from the pharmacy within 6 months after inclusion. Secondary outcomes include treatment uptake, virologic response, reinfection incidence, and resistance-associated substitutions.

Results:

The first study participant was included on 1 October 2019. As per 25 April 2021, 169 participants have been included. Patient recruitment will be completed by the end of October 2021 and preliminary results will be presented.

Conclusion:

Representing a novel model of care suited to reach and engage marginalized PWID in HCV care, this study will inform HCV elimination efforts locally and internationally. If the model proves efficacious and feasible, it should be considered for broader implementation.

Disclosure of Interest Statement:

HM and OD have received lecture and consultancy fees from Gilead, MSD and Abbvie. No pharmaceutical grants were received in the development of this study.

		STEPS								
		#1	#2	#3	#4	#5	#6	#7	#8	
CLUSTERS	#1									
	#2									
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Figure. The stepped wedge cluster randomized trial design of OPPORTUNI-C. Seven clusters will be sequentially assigned to change from standard of care to intervention in a random order. Blank cells represent control observations and shaded cells represent intervention observations. From Midgard et al. *Trials* 2020.