Sofosbuvir-Velpatasvir with Minimal Monitoring +/- HCV/HIV Coinfection
ACTG A5360 (MINMON)

Sofosbuvir-Velpatasvir with Minimal Monitoring +/- HIV Coinfection
ACTG A5360 (MINMON): Study Overview

• **Design**: Phase 4 open-label single-arm trial to examine the safety and efficacy of a minimal monitoring approach to HCV care delivery using 12 weeks of sofosbuvir-velpatasvir in treatment-naïve patients

• **Setting**: Multiple sites in Brazil, South Africa, Thailand, Uganda & United States

• **Entry criteria**:  
  - Chronic HCV infection as determined by HCV RNA >1000 IU/ml  
  - Treatment-naïve  
  - Age 18 or older  
  - HIV coinfection permitted  
  - Compensated cirrhosis permitted (FIB-4 ≥3.25, capped at ≤20% participants)  
  - Absence of coinfection with HBV

• **Primary End-point**: SVR ≥22 weeks post-treatment initiation

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ACTG A5360 (MINMON):

- No pre-treatment genotyping
- Cirrhosis determination based on Fib-4
- All treatment medication provided at entry
- No scheduled on treatment visits/labs
- Remote contact at weeks 4 and 22

No Genotype

Cirrhosis Status by Fib-4

All pills provided at Entry

Sofosbuvir-Velpatasvir (SOF-VEL)

Sofosbuvir-Velpatasvir with Minimal Monitoring +/- HIV Coinfection
ACTG A5360 (MINMON): Trial Design

**Drug Dosing**
Sofosbuvir-velpatasvir: 400/100 mg once daily
*Final analytic set was n = 399 since one study participant never started SOF-VEL
**SVR ascertainment permitted out to week 76 of study

# Sofosbuvir-Velpatasvir with Minimal Monitoring +/- HIV Coinfection
## ACTG A5360 (MINMON): Study Population

<table>
<thead>
<tr>
<th>Baseline Characteristic</th>
<th>Sofosbuvir-Velpatasvir (n = 399)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, median (range)</td>
<td>47 (20-82)</td>
</tr>
<tr>
<td>Female sex at birth, n (%)</td>
<td>139 (35)</td>
</tr>
<tr>
<td>Identity across transgender spectrum, n (%)</td>
<td>22 (6)</td>
</tr>
<tr>
<td>Race, n (%)</td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>166 (42)</td>
</tr>
<tr>
<td>Black</td>
<td>72 (18)</td>
</tr>
<tr>
<td>Asian</td>
<td>113 (28)</td>
</tr>
<tr>
<td>HCV RNA log_{10} IU/mL, median (IQR)</td>
<td>6.1 (5.6 – 6.6)</td>
</tr>
<tr>
<td>Current injection drug use, n (%)</td>
<td>12 (3)</td>
</tr>
<tr>
<td>Current alcohol use, n (%)</td>
<td>161 (40%)</td>
</tr>
<tr>
<td>Cirrhosis (by FIB-4 ≥3.25), n (%)</td>
<td>34 (9)</td>
</tr>
<tr>
<td>HIV coinfection, n (%)</td>
<td>166 (42)</td>
</tr>
<tr>
<td>Suppressed on antiretroviral therapy, n (% of HIV/HCV)</td>
<td>164 (99)</td>
</tr>
</tbody>
</table>

IQR, interquartile range; FIB-4, Fibrosis-4 index

Sofosbuvir-Velpatasvir with Minimal Monitoring +/- HIV Coinfection
ACTG A5360 (MINMON): Results, Overall and by HIV Status

Sofosbuvir-Velpatasvir with Minimal Monitoring +/- HIV Coinfection ACTG A5360 (MINMON): Results by Cirrhosis Status

Sofosbuvir-Velpatasvir with Minimal Monitoring +/- HIV Coinfection
ACTG A5360 (MINMON): Results by Injection Drug Use Status

Sofosbuvir-Velpatasvir with Minimal Monitoring +/- HIV Coinfection
ACTG A5360 (MINMON): Results by Age

MINMON Study: Sofosbuvir-velpatasvir with minimal monitoring
Results by HCV Genotype

MINMON Study: Sofosbuvir-velpatasvir with minimal monitoring

Study events

• 15 (3.8%) participants with following events:
  - n=3 adverse events (AE)
  - n=8 abnormal lab values at baseline
  - n=6 non-AE clinical events

• 3 participants reported losing medications
  - 1 after 14 days on study
  - 2 received replacement (interruption: 4 and 7 days)

• 2 participants reported premature discontinuation
  - One loss of medications, one due to AE

**Interpretation**: “In this diverse global population of people with HCV, the MINMON approach with sofosbuvir–velpatasvir treatment was safe and achieved SVR comparable to standard monitoring observed in real-world data. Coupled with innovative case finding strategies, this strategy could be crucial to the global HCV elimination agenda.”

Hepatitis C Online is funded by a cooperative agreement from the Centers for Disease Control and Prevention (CDC-RFA- PS21-2105). This project is led by the University of Washington Infectious Diseases Education and Assessment (IDEA) Program.

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