Separate clinical trials for co-infected patients are necessary

FOR THE MOTION

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Definition of « clinical trial »

« Combination of steps in which scientists do experiments with a health intervention in an attempt to find enough evidence for a process which would be useful as a medical treatment »

(Mix of FDA and Wikipedia 2015)
Definition of « endpoint »

« Occurrence of a disease, sign or laboratory value that constitutes one of the target outcome of the trial »

(again, Mix of FDA and Wikipedia 2015 !)
SVR

SVR4

SVR12

SVR24
HIV, HCV and the liver, A complex story

- Higher HCV chronicity rate
- Increased viral replication
- Decreased HCV-specific immune response

Fibrosis → Cirrhosis → HCC

- Direct effect on stellate cells
- Immune dysregulation
- Cytokine alteration
- Hepatocyte apoptosis

HAART

CD4 Depletion gut mucosa

Ingiliz & Rockstroh, Current Opinion HIV AIDS 2015
• 23 patients with fibrosing cholestatic hepatitis, of whom 4 were HIV
• 2 24W-regimen: SOF+DCV or SIOF+RBV
• Endpoint: complete clinical response

1 failure: HIV+ patient
Selection of patients for trials
Figure 1. Five-year rate (95% CI) of recurrence post-SVR, by risk group

Low risk
43 studies
N = 9,419
Avg. FU = 4.1 ± 2.1 y

High risk (IDUs/prisoners)
16 studies
N = 819
Avg. FU = 2.9 ± 1.6 y

HIV/HCV co-infected
7 studies
N = 833
Avg. FU = 3.1 ± 1.2 years

21.7%
(95% CI 18.3-25.5%)

13.2%
(95% CI 9.3-17.2%)

1.1%
(95% CI 0.9-1.4%)

Low risk
High risk
HIV/HCV co-infected

Hill A, CROI 2015
<table>
<thead>
<tr>
<th>Category</th>
<th>Incidence Rate</th>
</tr>
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<tr>
<td>NON IVDU</td>
<td>0</td>
</tr>
<tr>
<td>Non Spanish</td>
<td>2.3</td>
</tr>
<tr>
<td>Non HIV</td>
<td>2.3</td>
</tr>
<tr>
<td>Total</td>
<td>3</td>
</tr>
<tr>
<td>IVDU</td>
<td>4</td>
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<tr>
<td>20-29 yrs</td>
<td>4.2</td>
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<tr>
<td>HIV+</td>
<td>6.5</td>
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<tr>
<td>HIV+ And IVDU</td>
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<tr>
<td>HIV+, IVDU 20-29 yrs</td>
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