Acute Hepatitis C in the PROUD pilot study

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PROUD Pilot Study

Pre-exposure Option for reducing HIV in the UK: an open-label randomisation to immediate or Deferred daily Truvada for HIV negative gay men

http://www.proud.mrc.ac.uk/
Background

- Pre-exposure prophylaxis (PrEP) has proven biological efficacy to reduce the sexual acquisition of HIV\(^1\), but public health benefit is uncertain.
- Concerns about the effect of PrEP usage on risk behavior and acquisition of other STIs
- Excluding intravenous transmission, Hepatitis C (HCV) is almost exclusively found in HIV positive MSM. HCV testing is not routine in HIV negative MSM, so it is not included in the PROUD study

Methods

• **Past history of STIs** is collected at enrolment

• **STI screens** are conducted at six monthly intervals, but results from additional routine screens are collected at each visit (three monthly)

• HCV antibody and raised ALT were **not** exclusion criteria in PROUD

• Acute HCV **defined as**:
  - HCV RNA positive and anti HCV negative (with follow up)
  - HCV Ab/RNA positive with previous negative in 6 months
Results

- 393 participants enrolled by 31/12/2013
- 160 (41%) individuals had been tested on one or more occasion for HCV.
- HCV incidence in our cohort was 5/393:1.3%, and amongst those tested 5/160:3.1%.
## Case characteristics

<table>
<thead>
<tr>
<th>Site</th>
<th>Randomization ARM</th>
<th>Age</th>
<th>Time from enrolment to HCV diagnosis (Days)</th>
<th>HCV RNA Baseline</th>
<th>Indication for HCV Testing</th>
<th>Symptoms/ALT</th>
<th>STI since enrolment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brighton</td>
<td>Immediate</td>
<td>38</td>
<td>297</td>
<td>311905</td>
<td>Risk behaviour</td>
<td>NO</td>
<td>Yes</td>
</tr>
<tr>
<td>Barts</td>
<td>Immediate</td>
<td>39</td>
<td>28</td>
<td>11902147</td>
<td>Partner HCV (+)</td>
<td>NO</td>
<td>No</td>
</tr>
<tr>
<td>Manchester</td>
<td>Deferred</td>
<td>24</td>
<td>64</td>
<td>1684020</td>
<td>Symptoms</td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>STH</td>
<td>Immediate</td>
<td>38</td>
<td>29</td>
<td>9003</td>
<td>Partner HCV (+)</td>
<td>NO</td>
<td>No</td>
</tr>
<tr>
<td>KLC</td>
<td>Deferred</td>
<td>64</td>
<td>-28</td>
<td>1,641,554</td>
<td>IDU</td>
<td>NO</td>
<td>Yes</td>
</tr>
</tbody>
</table>
Time since last HCV negative to HCV diagnosis

Case #1
Case #2
Case #3
Case #4
Case #5

Screening
Randomization
Conclusions

- There was an unexpected number of aHCV cases.
- HIV prevention studies should consider including HCV testing at baseline and follow-up as part of testing for other STIs.
- Undiagnosed acute HCV infection in MSM reporting high risk sex is a public health concern.
- Routine testing of HCV and ALT in the list of routine STIs should be considered for this group.
Acknowledgements (1)

Study participants

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Acknowledgements (2)

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