1. Efficacy and safety of hepatitis A vaccines

1a) Full dose inactivated hepatitis A vaccine

**Author(s):** Wiersma S, Irving G, Ott J, Holden J  
**Date:** 2011-06-29  
**Question:** Should inactivated hepatitis A vaccine vs no intervention, inactive control or placebo be used for hepatitis A?  
**Settings:** General population

<table>
<thead>
<tr>
<th>Quality assessment</th>
<th>No of patients</th>
<th>Effect</th>
<th>Quality</th>
<th>Importance</th>
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<tbody>
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<td>Relative (95% CI)</td>
<td>Absolute</td>
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<td><strong>No of studies</strong></td>
<td><strong>Design</strong></td>
<td><strong>Risk of bias</strong></td>
<td><strong>Inconsistency</strong></td>
<td><strong>Indirectness</strong></td>
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</table>

¹ A large effect, RR=0.12, was found.  
² Innis 1994 reported that no hospitalizations or deaths were attributed to vaccination but did not provide full breakdown of reporting according to ICH GCP 1997.
References


### Live attenuated hepatitis A vaccine

**Author(s):** Wiersma S, Irving G, Ott J, Holden J  
**Date:** 2011-06-29  
**Question:** Should live attenuated hepatitis A vaccine vs no intervention, inactive control or placebo be used for hepatitis A?  
**Settings:** General population

<table>
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<tr>
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<td>Risk of bias</td>
</tr>
<tr>
<td>13 randomised trials</td>
<td>randomised trials</td>
<td>serious 1</td>
</tr>
</tbody>
</table>

**hepatitis A (follow-up 1-60 months; assessed with: clinical and laboratory criteria)**

| 13 randomised trials | randomised trials | serious 4 | very serious 4 | serious 4 | serious 5 | none | | 0/864813 (0%) | 0/799585 (0%) | - | - | ⊙⊙⊙O | VERY LOW | CRITICAL |

**absence of serious adverse effects (follow-up 1-60 months; assessed with: clinical observation)**

1. None of the studies had a low risk of bias when considering adequate sequence generation, allocation concealment, blinding, incomplete accounting of patients and outcome events. All studies reported on expected outcomes.  
2. I squared equals 80%.  
3. RR was 0.09 with over 1.6 million participants. A very large effect was found but due to downgrade factors this was not used to upgrade this study.  
5. Insufficient evidence was reported.
References


1c) Single dose inactivated hepatitis A vaccine

Author(s): Wiersma S, Irving G, Ott J, Holden J
Date: 2011-06-29
Question: Should single dose inactivated hepatitis A vaccine versus no intervention, inactive control or placebo be used for hepatitis A?
Setting: General population

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<td>Indirectness</td>
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</table>

\(^1\)Virosomal inactivated hepatitis A vaccine.

Reference

1d) Single dose live attenuated hepatitis A vaccine

**Author(s):** Wiersma S, Irving G, Ott J, Holden J  
**Date:** 2011-06-29  
**Question:** Should single dose live attenuated hepatitis A vaccine vs no intervention, inactive control or placebo be used for hepatitis A?  
**Settings:** General population

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<th>Inconsistency</th>
<th>Indirectness</th>
<th>Imprecision</th>
<th>Other considerations</th>
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<th>Importance</th>
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<tbody>
<tr>
<td>13</td>
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<td>Serious¹</td>
<td>serious²</td>
<td>no serious indirectness</td>
<td>no serious imprecision</td>
<td>none³</td>
<td>63/864813 (0.007%)</td>
<td>723/799585 (0.09%)</td>
<td>RR 0.09 (0.04 to 0.17)</td>
<td>-</td>
<td>⊕⊕OO LOW CRITICAL</td>
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</tbody>
</table>

¹ None of the studies had a low risk of bias when considering adequate sequence generation, allocation concealment, blinding, incomplete accounting of patients and outcome events. All studies reported on expected outcomes.  
² I squared equals 80%.  
³ RR was 0.09 with over 1.6 million participants.

**References**


\[1\] All four GRADE tables on hepatitis A vaccine safety and efficacy were prepared on the bases of a recently conducted Cochrane Review. References to individual studies are included at the end of each table.