Valacyclovir reduced genital herpes transmission in couples discordant for herpes simplex virus type 2 infection


Clinical impact ratings GP/FP/Primary care ★★★★★ Infectious diseases ★★★★★

In heterosexual couples who are serologically discordant for herpes simplex virus type 2 (HSV-2) infection, does once daily valacyclovir reduce the sexual transmission of genital herpes?

METHODS

- **Design:** randomised placebo controlled trial.
- **Allocation:** concealed.
- **Blinding:** blinded (participants, healthcare providers, data collectors, data analysts, and outcome assessors).
- **Follow up period:** 8 months.
- **Setting:** 96 sites in the US, Canada, Europe, Latin America, and Australia.
- **Participants:** 1498 couples ≥ 18 years who were immunocompetent, heterosexual, monogamous, in good health, and using effective contraception. One (source) partner had clinically symptomatic genital HSV-2 infection, presence of recurrent genital herpes with < 10 episodes/year, and non-use of any daily antiviral therapy. The other (susceptible) partner had HSV-2 seronegativity on Western blot analysis.
- **Intervention:** oral valacyclovir, 500 mg once daily (n = 743), or matching placebo (n = 741) for source partners. Both partners received counselling on safer sex practices and were offered condoms at monthly visits.
- **Outcomes:** laboratory confirmed clinically symptomatic first episode of genital HSV-2 infection (susceptible partner) and recurrence of genital HSV-2 infection (source partner).
- **Participant follow up:** 99% (1484 couples, median age 34.5 years, 67% women source partners; intention to treat analysis).

*See glossary.
†Information provided by author.

MAIN RESULTS

The table shows the results.

CONCLUSION

In heterosexual couples discordant for herpes simplex virus type 2 infection, valacyclovir reduced transmission of infection.

<table>
<thead>
<tr>
<th>Outcomes at 8 months</th>
<th>Valacyclovir</th>
<th>Placebo</th>
<th>Hazard ratio (95% CI)</th>
<th>NNT (CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptomatic HSV-2 infection in HSV-2 seronegative partners</td>
<td>0.5%</td>
<td>2.2%</td>
<td>0.25 (0.08 to 0.75)</td>
<td>62 (34 to 202)</td>
</tr>
<tr>
<td>Overall HSV-2 infection in seronegative partners</td>
<td>1.9%</td>
<td>3.6%</td>
<td>0.52 (0.27 to 0.99)</td>
<td>57 (29 to 1051)</td>
</tr>
<tr>
<td>HSV-1 or HSV-2 infection in seronegative partners</td>
<td>1.9%</td>
<td>4.2%</td>
<td>0.45 (0.24 to 0.84)</td>
<td>44 (24 to 174)</td>
</tr>
<tr>
<td><strong>RRR (CI)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Genital recurrence in seronegative partners</td>
<td>39%</td>
<td>77%</td>
<td>50% (45 to 55)</td>
<td>3 (2 to 3)</td>
</tr>
</tbody>
</table>

*Abbreviations defined in glossary; RRR, NNT, and CI calculated from data in article.

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Valacyclovir v placebo for symptomatic genital herpes simplex virus type 2 (HSV-2) infection

For information on this topic, please visit the following website: www.evidence-basedmedicine.com