EVALUATION OF NEURAL TUBE DEFECTS AFTER EXPOSURE TO RALTEGRAVIR DURING PREGNANCY

BACKGROUND AND OBJECTIVES

- Embryonic neural tube development occurs during the first 28 days after conception.
- Failure of neural tube to close leads to neural tube defects (NTDs), which are birth defects of the brain, spine, or spinal cord.
- among the 803 prospective reports, no cases of NTDs were identified among infants regardless of the presence of RAL exposure.
- Reports were classified as prospective or retrospective.
- 435 (35%) were reported retrospectively.
- As of 31-May-2018, 1256 pregnancy outcomes were reported for 1238 pregnancies in women exposed to RAL.
- Any RAL exposure: 0/803
- The majority of the first trimester exposures (202/443) were in women receiving RAL during the periconception period (within 28 days of conception).

RESULTS

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- All of the 803 prospective reports were related to 1238 pregnancies in women exposed to RAL.
- 443 (55%) documented first trimester as the earliest exposure.
- The majority of the first trimester exposures (202/443) were in women receiving RAL during the periconception period (within 28 days of conception).

MARRIS Prospective Reports (n=443)

<table>
<thead>
<tr>
<th>Exposure Period</th>
<th>NTDs</th>
<th>Total Exposures</th>
<th>NTDs/Total Exposures</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st trimester</td>
<td>0</td>
<td>443</td>
<td>0/443</td>
</tr>
<tr>
<td>Periconception</td>
<td>0</td>
<td>202</td>
<td>0/202</td>
</tr>
</tbody>
</table>

MARRIS Retrospective Reports (n=435)

<table>
<thead>
<tr>
<th>Exposure Period</th>
<th>NTDs</th>
<th>Total Exposures</th>
<th>NTDs/Total Exposures</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st trimester</td>
<td>0</td>
<td>184</td>
<td>0/184</td>
</tr>
<tr>
<td>Periconception</td>
<td>0</td>
<td>161</td>
<td>0/161</td>
</tr>
</tbody>
</table>

CONCLUSIONS

- There were no reports of NTDs among 1991 prospective reports of RAL exposure in pregnancy, which was in the periconception period.
- One retrospective report of myelomeningocele was identified among live births following periconception exposure to RAL.

The available data do not indicate an association between RAL exposure and NTDs.

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