Anastrozole plus leuprolinel in early maturing girls with compromised growth: the "GAIL" study

Table 1: Patient characteristics (mean ± SEM)

<table>
<thead>
<tr>
<th>Group</th>
<th>Age (yrs)</th>
<th>Height (SDS)</th>
<th>BMI (SDS)</th>
<th>TH (SDS)</th>
<th>TH-PAR (SDS)</th>
<th>Bone age advancement (years)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A: LHrHa + A1 (n = 20)</td>
<td>8.91 ± (5.98)</td>
<td>0.35 (±0.89)</td>
<td>0.35 (±1.08)</td>
<td>0.35 (±0.72)</td>
<td>0.35 (±0.92)</td>
<td>0.35 (±0.72)</td>
</tr>
<tr>
<td>B: LHrHa (n = 20)</td>
<td>8.6 (±0.67)</td>
<td>0.37 (±0.8)</td>
<td>0.37 (±0.8)</td>
<td>0.37 (±0.8)</td>
<td>0.37 (±0.8)</td>
<td>0.37 (±0.8)</td>
</tr>
</tbody>
</table>

P = 0.010

Evolution of Predicted Adult Height (PAH) and Bone Age Advancement (BAA) in the 10 girls that continued for 2.5 years with anastrozole monotherapy 1 mg/day

The 20 girls on combination therapy after completion of the initial phase, were randomized in 2 subgroups:

<table>
<thead>
<tr>
<th>Group</th>
<th>BMI</th>
<th>TH</th>
<th>PAH cm</th>
</tr>
</thead>
<tbody>
<tr>
<td>A1</td>
<td>1.10</td>
<td>150.96</td>
<td>153.36</td>
</tr>
<tr>
<td>A2</td>
<td>1.10</td>
<td>150.96</td>
<td>153.36</td>
</tr>
</tbody>
</table>

P = 0.12 | 0.31 | 0.31 |

Fig. 2: Reduction in bone age advancement (BAA) years; left y-axis and gain in predicted adult height (PAH) (SDS; right y-axis) in group A (LHrHa + A1) and group B (LHrHa) at 12, 18, 24 months.

Conclusions

In early maturing girls with compromised growth, treatment for 2 yrs or until the age of 11 yrs with LHrHa + anastrozole 1 mg/day

- gain of +0.7 cm in total when treated with anastrozole monotherapy until they reach NAH
- that is +0.3 cm more than
- the gain of +1.4 cm if they do not continue with anastrozole monotherapy
- and +0.1 cm more from those treated with an LHrHa alone
- who gain only +0.5 cm

As a result, the combination therapy continued with anastrozole monotherapy, ends in the shortest distance from target height

- 4.7 cm (from 14.48 to inclusion)
- compared with 5.7 cm (from 13.68 at inclusion)
- and 8.7 cm from 12.82 in girls treated with an LHrHa alone

Which implies that the addition of anastrozole to an LHrHa analogue apart from being safe, is effective in ameliorating substantially Near Adult Height making the intervention meaningful.