Clinical investigation with a new triphasic oral contraceptive

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The extended clinical trial of the two triphasic preparations SH B 264 AB and SH B 261 AB for contraceptive reliability, cycle control and tolerance was carried out in different countries: Austria, the Netherlands, Peru, Venezuela and West Germany. Both clinics and gynaecologists in private practice participated in the trial.

Generally, women were selected on the basis of their meeting the requirements for the prescription of oral contraceptives in accordance with established medical practice. The participants were allocated to the preparations in a randomized fashion and were instructed to use the oral contraceptive as follows: Intake from the first package was to start on the first day of the cycle. After finishing the first calendar package, an interval of 7 days had to be observed as usual, before starting the next package. Before starting medication, all women were told that the first medication cycle would have a duration of only about 23 to 25 days.

RESULTS OF THE COMPARISON

Test preparation SH B 264 AB was given to 696 women for a
total of 6628 cycles. The version SH B 261 AB was given to 634 women for 6025 cycles.

During the computer evaluation of the period of use of SH B 264 AB, no pregnancies were recorded, despite the fact that medication errors (one or several omission of tablets) were admitted. During medication with SH B 261 AB there was one pregnancy, which had to be evaluated as 'drug failure'.

Both preparations were equally well tolerated, but the incidence of spotting and intermenstrual bleeding episodes was somewhat lower for SH B 264 AB than for SH B 261 AB (see Table 7.1).

Table 7.1  Intermenstrual bleeding rate, calculated in terms of the total number of cycles, in %

<table>
<thead>
<tr>
<th></th>
<th>SH B 264 AB</th>
<th>SH B 261 AB</th>
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<tbody>
<tr>
<td>Spotting</td>
<td>4.6</td>
<td>5.1</td>
</tr>
<tr>
<td>Breakthrough bleeding</td>
<td>2.0</td>
<td>2.5</td>
</tr>
<tr>
<td>Spotting and breakthrough bleeding*</td>
<td>1.2</td>
<td>1.3</td>
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*Beginning as spotting and only later turning into heavier bleeding

Though the differences between the 2 triphasic versions are not large, it was decided to give preference to the preparation SH B 264 AB. The main reason for our decision was that this preparation, with its markedly lower total oestrogen dose per cycle (0.68 mg as against 0.83 mg ethinyloestradiol in SH B 261 AB), meets the criterion of the lowest possible dose of both hormone components more closely than the comparison drug.

The following discussion gives a brief summary of the test data for SH B 264 AB.

**Duration of treatment**

The medication was used by 594 women ( = 85.3% of all test persons) for 6 cycles, by 362 women (52%) for 12 cycles, and by