## Title of trial:
Determination of clenbuterol in plasma of mother and child after intravenous infusion of clenbuterol before birth

## Investigator:
Dr. Wiest

## Trial sites:
1

## Diagnosis and main criteria for inclusion:
Women who had to deliver by caesarian section

## No. of subjects:
enrolled: 3 patients

## Test product:
clenbuterol

dose:
0.04 µg clenbuterol/kg body weight/min (total dose approx. 80 µg)

mode of admin.:
Intravenous infusion

## Reference therapy:
n.a.

## Duration of treatment:
30 minutes

## Criteria for evaluation:
Concentration of clenbuterol in the plasma of the mother, clenbuterol concentration in the plasma of the child

## Efficacy / clinical pharmacology:
n.a.

## Safety:
n.a.

## Statistical methods:
Descriptive statistics

## SUMMARY – CONCLUSIONS:
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<th>Tabulated Trial Report</th>
<th>Synopsis No.:</th>
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Whilst the plasmas of 2 patients and their babies were easily analyzed, the plasma extracts of the 3rd patients contained unknown substances which considerably impair the accuracy of the analyses.

At the end of the infusion the concentration of clenbuterol in the plasma of the mothers (n = 2) was 0.7 mg/ml. After the birth (1 h 15 min and 1 h 27 min after the end of the infusion) the clenbuterol concentration in the maternal plasma had dropped to 0.31 mg/ml the clenbuterol concentration in the infantile plasma was 0.21 ng/ml.

Efficacy / clinical pharmacology results: n.a.

Safety results: n.a.

Conclusions: Based on the data obtained no meaningful conclusions regarding plasma concentrations of clenbuterol can be drawn.