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VON HOLST T

*Efficacy and tolerability of a new 7-day combination patch in sequential combined HRT in comparison to placebo*

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# EFFICACY AND TOLERABILITY OF A NEW 7-DAY COMBINATION PATCH IN SEQUENTIAL COMBINED HRT IN COMPARISON TO PLACEBO

SESSION 5:  
PRACTICAL  
ASPECTS OF  
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HRT 2

## INTRODUCTION

The aim of this randomized, placebo-controlled multicentre study was to investigate the efficacy of a new 7-day patch regime in the treatment of postmenopausal women with climacteric complaints in comparison to placebo. Secondary target variables for investigation were patch adhesiveness, skin tolerability and effect on lipid profile.

## MATERIAL AND METHODS

179 symptomatic, postmenopausal, non-hysterectomized women, aged 40–65 years with serum concentrations of FSH > 30 U/l and E2 < 30 pg/ml, were randomized to either active treatment or placebo for 3 cycles followed by a further 3-month open follow-up with active medication for all patients.

Active treatment was a 7-day mono estradiol (E2) patch providing 50 µg/day during week 1 and 2, and a 7-day combination patch system delivering 50 µg E2 and 10 µg levonorgestrel/day

during week 3 and 4 of treatment cycle.

## RESULTS

In both groups (active treatment and placebo) a reduction in postmenopausal complaints (Kupperman Index) was observed. Despite the notable decrease in the placebo treated group, the active group was statistically superior at the end of cycle 1 ( $p < 0.02$ ) and cycle 3 ( $p < 0.0001$ ) (Fig. 1).

The number of hot flushes showed a decrease of approximately 50 % in the placebo group, but the active treatment group was superior again, with statistically significance from the 4<sup>th</sup> up to the 12<sup>th</sup> week of treatment ( $p < 0.003$ ) (Fig. 2).

The patches were assessed for patch adhesiveness on a weekly basis. The investigators' assessment revealed sufficient patch adhesiveness in more than 90 % of the patients.

Patients also assessed skin reaction and pruritus on a weekly basis. No or slight skin reactions were seen in 94.7 % of patch ap-

plications, severe skin reactions were seen in only 1 % (Tab. 1).

A decrease in the concentrations of total cholesterol, triglycerides and LDL-cholesterol was observed in the treated group; there was no change in the HDL-cholesterol fraction (Tab. 2).

There was no difference in the body weight between the active and placebo group, but an increase of about 1 kg in both groups after 6 months of treatment.

Allover, the subjective acceptance of the patches by the patients was good to very good in respect to handling, appearance and convenience of use (82 %). The majority of patients (69 %) were willing to consider continuing treatment with these 7-day patches at the end of the study.

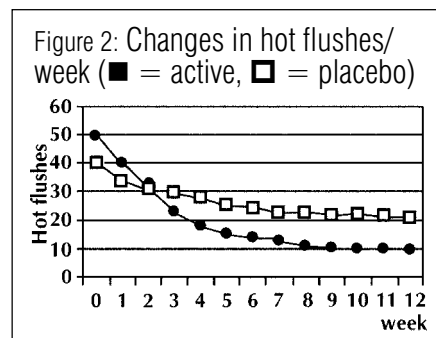
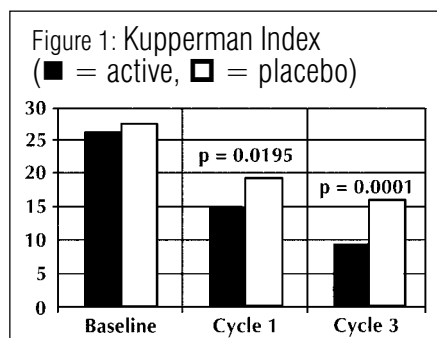


Table 1: Skin reactions all mono and combi patch applications

|                                     | n           | %            |
|-------------------------------------|-------------|--------------|
| No                                  | 1782        | 68.6         |
| Slight                              | 678         | 26.1         |
| Moderate                            | 111         | 4.3          |
| Severe                              | 26          | 1.0          |
| <b>Total # of evaluated patches</b> | <b>2597</b> | <b>100.0</b> |

Table 2: Lipid effects – active group

|                           | Baseline | Cycle 6 |
|---------------------------|----------|---------|
| Total cholesterol (mg/dl) | 252      | 240     |
| Triglycerides             | 113      | 103     |
| LDL (mg/dl)               | 181      | 165     |
| HDL (mg/dl)               | 57       | 59      |

**Professor Dr. med. Thomas von Holst**

Thomas von Holst graduated from the University of Heidelberg, Germany in 1970 with a medical degree. Following this, he took up the position of Assistant Physician for 1 year in the Surgical Department at Theresien Hospital in Mannheim, Germany. He then spent 4 years as Assistant Physician in the Gynecology Department at the Women's University Hospital in Heidelberg. In 1976, Professor von Holst moved to the Gynecology and Endocrinology Department of Ruprecht-Karls University in Heidelberg, where he took up the position of Assistant Head Physician and was later promoted to Managing Head Physician in 1982. He was then appointed to Professor in 1989 at the Women's University Hospital at Ruprecht-Karls University.

Professor von Holst is a founding member of the International Menopause Society (1978) and, in 1999, he was elected president of the German Menopause Society for 3 years.

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**CONCLUSION**

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- The new 7-day estradiol/levonorgestrel combi patch was statistically significant superior to placebo in the treatment of climacteric complaints
- The reduction in hot flushes was given for the full length of the 7-day treatment period
- The patch adhesiveness as well as skin tolerability was good
- A decrease in total cholesterol, triglycerides and low density lipoprotein was observed
- The majority of women was satisfied with the treatment of the new 7-day combination patch.

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