PAXMAN
SWISS CLINICAL
STUDIES OF EFFICACY
Non-randomised prospective controlled study between July 2009 and October 2011, in patients at 27 sites in Switzerland.

**Results**

Kaplan-Meier estimate to reach the combined end point (alopecia WHO III/IV and/or wearing a wig) showing Paxman Scalp Cooling Systems and gel caps have a significantly reduced risk of alopecia by 78%.

**T tolerability**

Was reported by 3.3% of patients for Paxman Scalp Cooling System and gel cap combined.

Patients questionnaire showed low incidences of freezing and unpleasant feelings.
On a six-point scale (1=good to 6=bad), with respect to global impression of therapy, end of study patients on rated:

- PAX: 4.5±1.6; on.
- Gel cap: 4.6±1.4; and on.
- No cooling: 4.1±1.9.

The respective grading marks (same scale) in the three groups were very similar.

Risk of alopecia is significantly reduced (70%) when using either the Paxman Scalp Cooling System or gel cap compared to no cooling.

In particular, alopecia is reduced by these two cooling devices when docetaxel is administered every 3 weeks.

Since with no protection, the majority of patients receiving docetaxel (every 3 weeks) will temporarily lose all their hair, and the study confirms that scalp cooling is an effective measure to prevent alopecia in these patients.
## Materials & methods

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Patients could choose depending on local availability of alopecia prevention from the following options:

Alopecia prevention using the Paxman Scalp Cooling Systems (PAX) model PSC-2
- Pre-infusion cooling 15 minutes.
- Cooling was maintained during the infusion period.
- Post-infusion cooling 90 minutes (45 minutes according to amended temperature).

Alopecia prevention cold cap (manufacturer not specified)
- Pre-infusion cooling 15 minutes.
- Cooling was maintained during the infusion period.
- Post-infusion cooling 90 minutes (45 minutes according to amended temperature).
- Gel caps have to be exchanged after the first 25 minutes of treatment, after another 45 minutes, and every 60 minutes thereafter (the cooling temperature was not prespecified for gel caps).

No alopecia prevention (no cooling group)
Patients refusing cooling treatment did not receive any alopecia prophylaxis but were also documented, provided they gave consent.
