
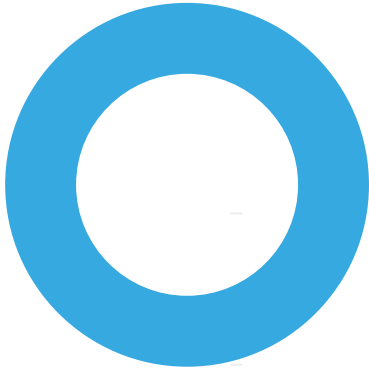


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PAXMAN  
**SWISS CLINICAL**  
STUDIES OF EFFICACY

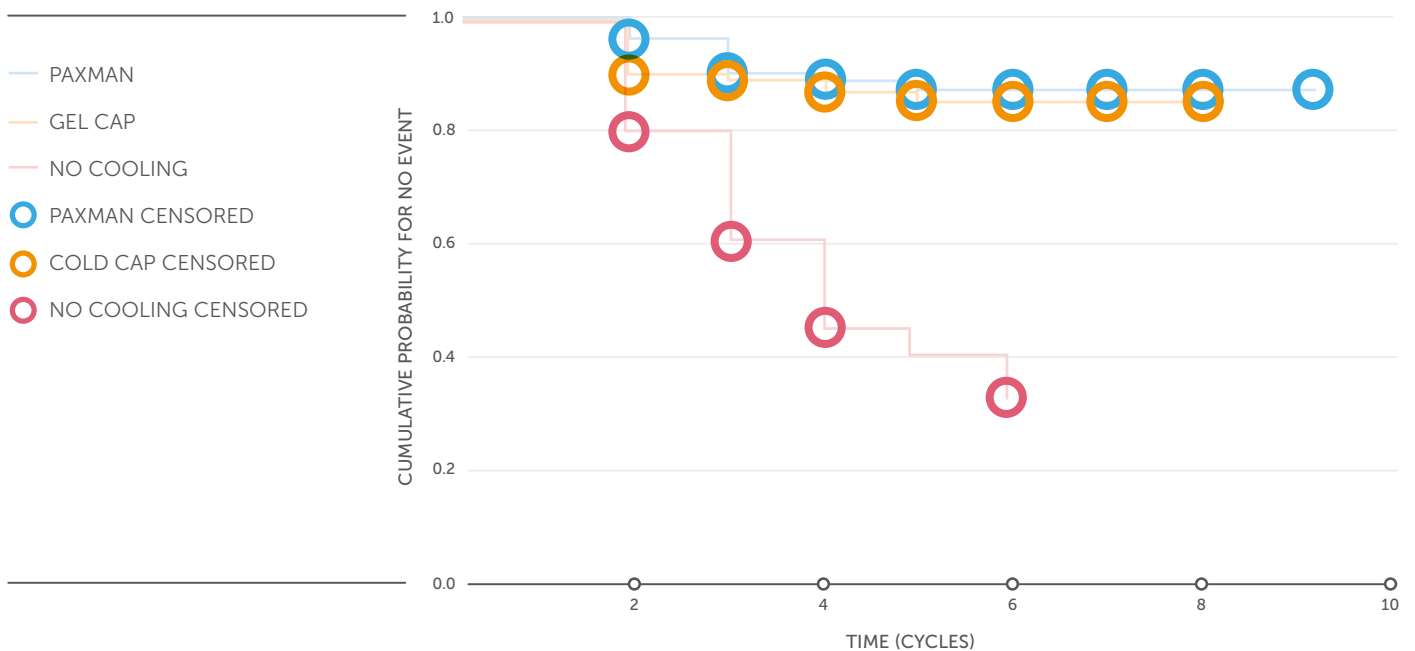
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Non-randomised prospective controlled study between July 2009 and October 2011, in patients at 27 sites in Switzerland.

## 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%.



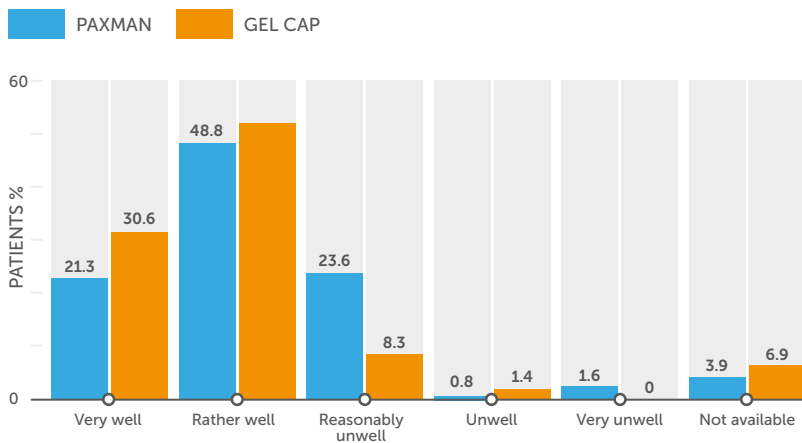
## Tolerability

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.



## Patient assessment and overall patient rating.



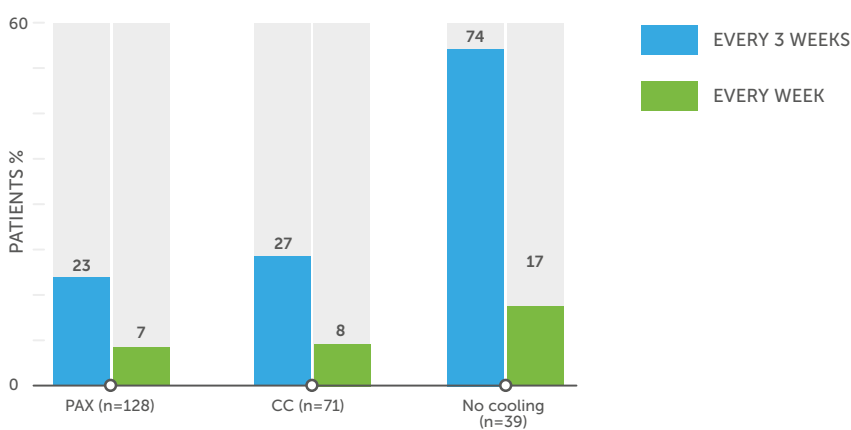
### 93.7% of patients' assessment of the cooling was above reasonably well.

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.

## Incidence of combined end point (alopecia WHO III/IV and/or wearing wig) by docetaxel treatment schedule.



- 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.












# 93.7%

patient assesment  
of scalp cooling was  
above reasonably well.

## Materials & methods

### Consultant/Medical Oncologist

### Hospital Sites

D. C. Betticher	—  —	Clinics of Medical Oncology, HFR Fribourg Cantonal Hospital, Fribourg, Switzerland
G. Delmore	—  —	Medical Oncology, Canton Hospital of Frauenfeld, Frauenfeld, Switzerland
U. Breitenstein	—  —	Onkozentrum Zürich, 8038 Zürich, Switzerland
S. Anchisi	—  —	Departement of Oncology, Sion's Hospital, 1951 Sion, Switzerland
B. Zimmerli-Schwab	—  —	Service of Oncologie, Pourtalès Hospital, 2000 Neuchâtel, Switzerland
A. Müller	—  —	Medical Oncology, Canton Hospital, 8400 Winterthur, Switzerland
R. von Moos	—  —	Medical Oncology, Canton Hospital to gray alliances, 7000 Chur, Switzerland
A. M. Hügli-Dayer	—  —	Oncological Practise, Rue De-Candolle 18, 1205 Genève, Switzerland
H. Schefer	—  —	OnkoZentrum Luzern, Hirslanden Klinik St. Anna, 6006 Luzern, Switzerland
S. Bodenmann: V. Bühler	—  —	Sanofi-Aventis (Suisse) SA, 1214 Vernier, Switzerland
R. R. Trueb	—  —	Dermatological Practise and Hair Centre, Bahnhofstrasse 1 a, 8304 Wallisellen, Switzerland

238 patients participated in this study (all with several types of cancer; breast, lung, prostate and others).

- 128 PAX (Paxman Scalp Cooling Systems, PSC-2).
- 71 gel caps (cold caps).
- 39 no cooling.

### Chemotherapeutic regimen:

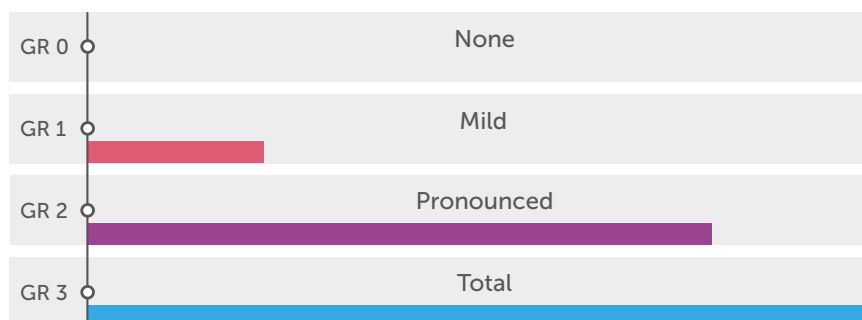
All patients except for 1 received docetaxel chemotherapy, alone or in combination with other agents.

Patient gender and age range was:

	PAX (n=128)	CC (n=71)	No cooling (n=39)
Age	67	64	67
Male	77	33	23
Female	51	38	16

WHO scoring system used to determine hair loss by this observational study.

Hair loss graded according to criteria:



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.



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PIONEERS IN SCALP COOLING