"Randomised controlled trial of Scalp Cooling (SC) for the prevention of Chemotherapy Induced Alopecia (CIA)"

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Background:

- **Chemotherapy Induced Alopecia** (CIA) is the most visibly distressing chemo Side effect
- The only randomized trial of SC to prevent CIA did not evaluate its effect on hair regrowth (HR) and was conducted in a predominantly taxane (T) treated population.
- We conducted a randomized trial of SC in a setting of anthracycline (A) and taxane chemotherapy and assessed its effect on CIA and HR

Aims:

To test if, the Paxman Scalp Cooling System is safe and effective in reducing chemotherapy-induced alopecia in woman with non-metastatic breast cancer undergoing neoadjuvant or adjuvant anthracycline and/or taxane based chemotherapy.

Methods:

Eligibility Criteria:

•Non-metastatic breast cancer women undergoing (neo) adjuvant chemotherapy

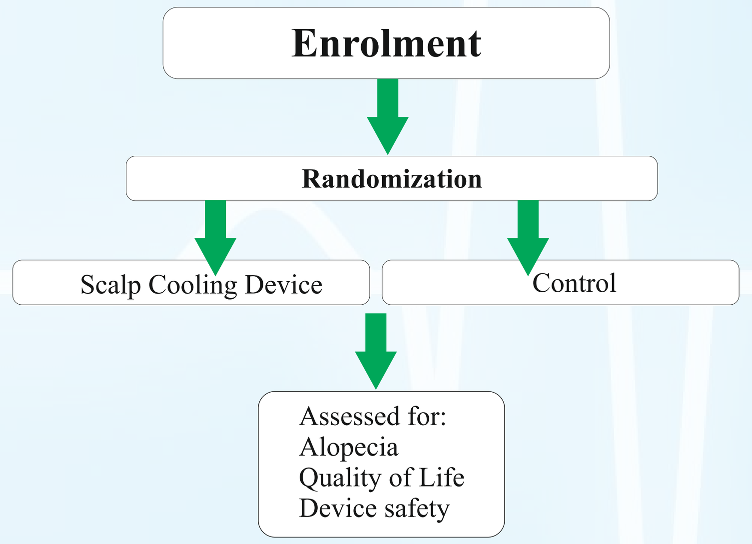
Primary Endpoint:

•To compare success in hair preservation, between the Paxman Scalp Cooling System and control (no cooling) after 4 cycles of anthracycline and/or taxane based chemotherapy (by means of CTCAE v4.0).

Secondary endpoints:

Hair Regrowth at 6 and 12 weeks after completion of chemotherapy, adverse events and comparative quality of life scores

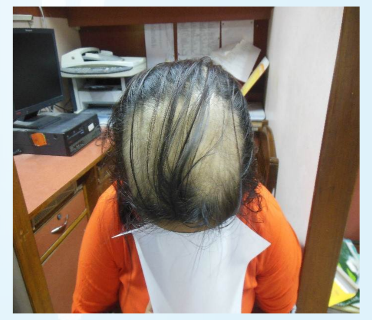
Schema



Alopecia Grading: CTCAE Version 4.0

Grade 0
No hair loss

Grade 1
Hair loss of up to 50% of normal, no wig required

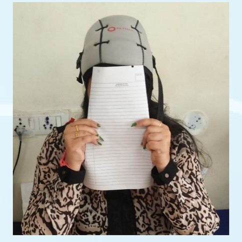


Grade 2
Hair loss of > 50% of normal, wig required

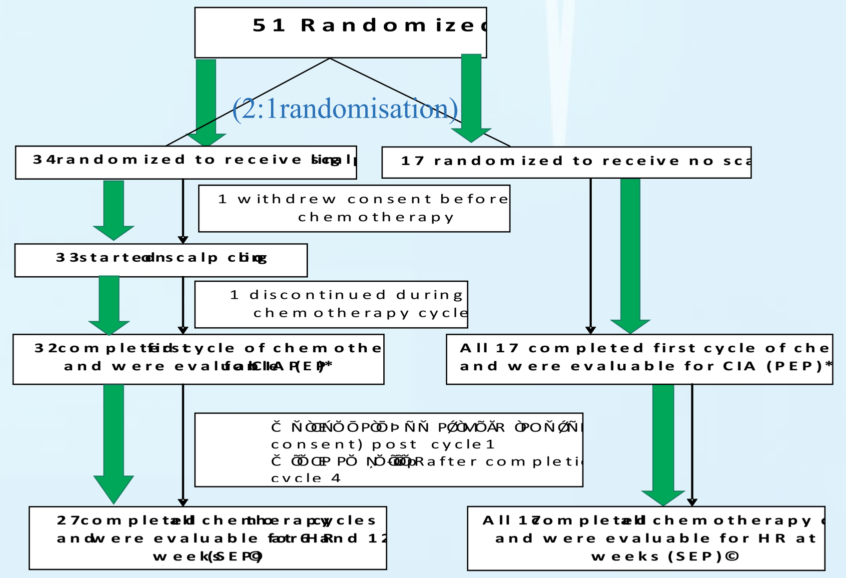
Method:

- Prior to scalp cooling, the cooling cap is disconnected from the coolant lines and is attached to the subject's head so as to covers the entire scalp with the cap
- Then the cap is connected to the coolant lines and powering on the system activate the refrigeration unit to decrease coolant temperature

- **Sc continued, standardized pre-cooling time of at least 30 mins, during chemotherapy, and a standardized post-cooling time of at least 90 mins**



Results:
Consort Diagram



Results: Baseline Characteristics

Parameter	No. (%) of Patients	
	Cooling(n=32)	NonCooling (n=17
Age[Median(range)]	37(21-49)	44(30-58)
Menopausal status		
Premenopausal	29(91)	13(77)
Postmenopausal	03(9)	04(23)
Body Mass Index [Median(range)]	24.19 (17.03-31.88)	27.3 (21.77-43.14)
Chemotherapy Regimen sequence		
Anthracycline f/b Taxane	15 (47)	09 (53)
Taxane f/b anthracycline	17 (53)	08 (47)
Breast Cancer Stage		
Early	19(59)	11(65)
LABC	13(41)	06(35)
Family history		
Yes	09 (28)	05 (29)
No	23 (72)	12 (71)

Results:efficacy

- Hair preservation (HP) rate was significantly higher in SC arm (18/32, 56.3%) compared to control arm (0/17, 0%; difference 56.3%, 95% CI 31%-73%, P=0.000004).
- Hair Regrowth (HR) was higher in SC arm compared to control at 6 weeks (89% vs 12%; difference 77%, 95% CI 49%-88%, p<0.001) and 12 weeks (100% vs 59%; difference 41%, 95% CI 8%-64%, p=0.0003).
- Hair preservation after 4 cycles was higher in patients receiving T versus those receiving A (77% vs 33%, p=0.0307)

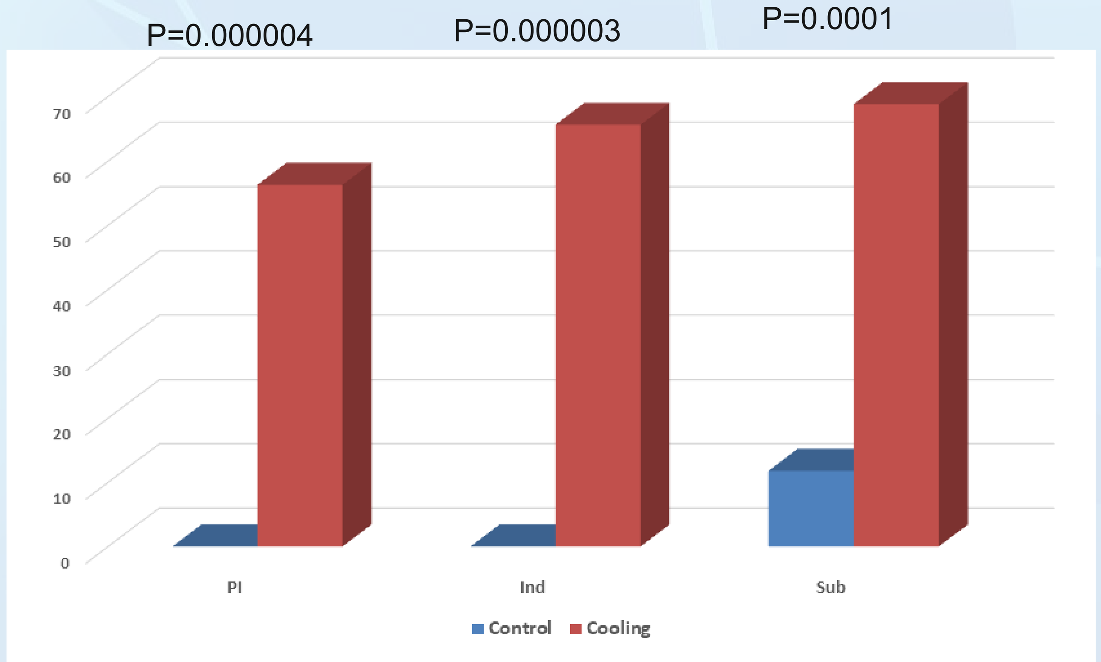
Scalp cooling with the Paxman Cooler System versus control

Scalp cooling with the Paxman Cooler System versus control

Concordance rate for CIA and Head cover use

- The concordance rate with Clinician and Independent Observer with regard to successful HP was 0.914 (0.798-1.000) at PEP and 0.858 (0.703-1.000) at 6 weeks
- Subject concordance rate was 0.754 (0.575-0.933) at PEP and 0.858 (0.703-1.000) at 6 weeks
- There was compulsion to use head covers/wigs by 15 (46.9%, 95% CI: 30.9-63.6) of the patients who received SC and 17 (100%, 95% CI: 81.6-100) among controls (*P = 0.0001*).

Primary End Point: CIA prevention



Quality of life and Adverse Events

- Patient reported hair loss at primary endpoint evaluation landmark was significantly lower in SC versus control arm (45% vs 82%, p=0.016) with compulsive head cover use of 47 % in SC vs 100% in controls (p= 0.0001).
- Of 33 patients who started on SC, 23(69%) patients experienced grade 1-2 cold related adverse effects in SC arm with no grade 3-4 events
- At median follow up there were no scalp metastasis noted.
- The participants will be followed up, according to routine institute practice, for long term safety and overall survival.
- This will validate long term safety issues in in locally advanced and high risk patients like our population

Limitations

- The most rate limiting step in the use of SC in patients in high turn over centers especially in most LMICs would be the lack of space and time.
- The treatment time would also be considerably longer consisting of precooling for 30 minutes, followed by administration of chemo and 90 minutes post chemotherapy ooling period (around 3-4 hours in total).
- Reimbursement of scalp cooling is not so far offered by insurance companies (Cost USD 50 to 75 per cycle in India).

Conclusions:

Women with breast cancer receiving A or T chemotherapy were significantly more likely to have <50% hair loss after chemotherapy, had superior hair regrowth and improved patient reported outcomes, if scalp cooling was used.

References:

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