Preliminary results of a long-term clinical follow-up of breast cancer patients treated with photobiomodulation therapy to prevent acute radiodermatitis (TRANSDERMIS trial)

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BACKGROUND

Photobiomodulation therapy (PBMT) ^[1]

- Light therapy: visible and/or (near)-infrared light (600-1000 nm)
- Light sources: laser diodes or light-emitting diodes (LED)
- Effect: stimulates wound healing and reduces inflammation and pain
- Scientific evidence: proven beneficial effect of PBMT in the prevention of radiation dermatitis (RD) in breast cancer (BC) patients ^[2,3]

Radiation dermatitis (RD) ^[4]

- Inflammatory skin reaction
- Affects 90-95% of the patients undergoing radiotherapy (RT)
- Diminishes patients' quality of life
- No general consensus guidelines on the treatment of RD

AIM

Evaluate the disease-free (DFS) and overall survival (OS) of BC patients treated with PBMT for RD

METHODS

Study design

Randomized, placebo-controlled trial with BC patients treated with an identical RT regimen post-lumpectomy at the Limburg Oncology Center (Jessa Hospital, Hasselt, Belgium) (NCT02443493) ^[2]

Placebo group	PBMT group
Standard skin care Placebo laser	Standard skin care PBMT
RT (25x2Gy + 8x2Gy)	RT (25x2Gy + 8x2Gy)

PBM parameters

Model	MLS® M6 (ASA srl)
Wavelength	808-905 nm
Fluence	4 J/cm ²
Treatment area	Whole breast, axilla, inframammary fold
Frequency	2x/week
Timing	During complete RT course

Outcome measures

- Appearance and date of local and/or regional recurrence
- Appearance and date of secondary tumors
- Appearance and date of distant metastasis
- Date of death of any cause

Evaluation schedule

RESULTS

Median follow-up (months)	Endpoint	Placebo group (n= 47)	PBMT group (n=46)	*P-value
32 (1-47 range)	DFS	98 %*	96 %§	1
	OS	100 %	100 %	1

*p < 0.05, log-rank test; ♦ 1 patient with contralateral BC; § 1 patient with uterine metastasis and 1 with contralateral BC; DFS, Disease-free survival; OS, Overall survival ; BC, breast cancer

CONCLUSION

Based on preliminary results of a short follow-up period, PBMT does not significantly influence the locoregional recurrence, the development of secondary tumors, or the OS in post-lumpectomy BC patients treated with RT

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REFERENCES

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