A single-arm, open label, single center study to evaluate the safety and clinical outcome of using FR-Mask in breast cancer patients with radiation-irritated skin.

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BACKGROUND

Breast radiotherapy after breast-conserving surgery reduces the risk of recurrence and death and is widely used as standard treatment for breast cancer. Radiation-irritated skin is a treatment-induced symptom caused by radiation dose-limiting toxicity. It damages skin structure and causes a variety of symptoms, including cuticle thinning, sweat gland damage, sebaceous gland damage and basal membrane damage. Radiation-irritated skin can greatly impact quality of life (QOL). Previous studies have shown that deer antler velvet extract possess inflammatory function and promotes repair of damaged follicles, sweat glands and sebaceous glands. And biocellulose membrane is a highly efficient media to introduce velvet extract to damaged skin tissue. FR-Mask is a breast mask combines bio-cellulose membrane, velvet extract and other active ingredients, such as COENZYME Q10 and allantoin. In this study, FR-Mask will be used in breast cancer patients to test the safety and efficacy to alleviate their radiation-irritated skin symptoms.

METHOD/TRIAL DESIGN

Patients who complete the post-operative radiotherapy and meet the inclusion and exclusion criteria will be enrolled into the study after the study team obtains their informed consent. Each subject will receive 12 packages of FR-Mask (1 mask in each individual package) and be instructed to put the patch on the irritated-skin area caused by radiation for 20 minutes every 3 days. Subjects will need to come back to clinics for evaluation every 4 weeks for 3 months. Up to 10 subjects will be enrolled in this study. Subjects will also be asked to come back to clinics after completion of the treatment period for 3 months. The total study duration for each subject will take 4.5 months. This study is a feasibility and pilot trial to test the safety and efficacy to alleviate their radiation-irritated skin symptoms, and will be conducted in China Medical University Hospital.

RESULT

This clinical trial was conducted on 10 patients hospitalized in China Medical University Hospital from October 2019 to March 2020. Compliance rate was 100 percent for these 10 breast cancer patients. The average age was 47.6±7.9 years. Among visits, there were no significant differences in the physical examination. No significant differences was reported in QoL questionnaire responses, however, the use of FR mask has a trend to reduce breast sensitivity and skin itching. To determine the effect of the product, differences of skin responses between the affected breast and the healthy breast were calculated, and then the differences of skin responses in the baseline visit were compared with the differences of skin responses in the follow-up visit. No serious or clinically adverse drug reactions (ADRs) were reported.

Appendix 1. Study Schedule

Visit	Treatment					Follow up period
	Screening	Visit 1 (baseline)	Visit 2	Visit 3	Visit 4 (EOT¥)	1month
Study Day*	Day -14	Day 1 (±2 Days)	Day 29 (±2 Days)	Day 57 (±2 Days)	Day 85 (±2 Days)	Day 113 (±2 Days)
Informed Consent	X					
Medical History (past 2 years)		X				
Physical Exam		X	X	X	X	X
Demographic Data		X				
Concomitant Medication		X	X	X	X	X
Vital Sign		X	X	X	X	X
Inclusion/Exclusion criteria	X	X				
FR-Mask Accountability		X	X	X	X	
FR-Mask and Patient Diary Dispense		X	X	X		
Patient Diary Review			X	X	X	
Study Questionnaires		X	X	X	X	X
Skin observation		X	X	X	X	X
AE/SAE monitoring			X	X	X	X

SUMMARY / CONCLUSION

FR mask is a safe and feasible material to apply on breast cancer patients after breast radiotherapy. The efficacy of FR mask in improving radiation-irritated skin has yet to be evaluated

TRIAL REGISTRATION

NCT04190381. Registered on December 9, 2019.

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