

Table 1. Schedule of enrolment, interventions, and assessments from the Alantel study

	STUDY PERIOD					
TIME POINT	Enrolment	Allocation	Post-Allocation			Close-out
	t=0	t=0	t1= 5 day start RT	t2= 10 day start RT	t3= 15 day start RT	t4= 22 day after RT
ENROLMENT:						
Eligibility screen	x					
Informed consent	x					
Allocation		x				
INTERVENTIONS:						
Alantel (Experimental group)		x	x	x	x	x
Placebo (Control group)		x	x	x	x	x
ASSESSMENTS						
List baseline variables						
Assigned group		x				
Sociodemographic data		x				
Previous history of dermatitis		x				
List outcome variables						
Presence/absence of radiodermatitis (RD)			x	x	x	x
Toxicity Level (ORTG Criteria)			x	x	x	x
Degree of discomfort with RD			x	x	x	x
Quality of life related to health			x			x
Presence of adverse events			x	x	x	x
List other data variables						
Symptoms and signs of RD			x	x	x	x
RD evolution time			x	x	x	x

Table 2. Primary and secondary outcomes

Primary outcomes	Measuring instruments/Definitions
Incidence of RD	Patients with radiation-induced dermatitis (RD)
Evaluation of the skin lesion (RD)	1) remains the same or worsens; 2) partial improvement; 3) total improvement or complete cure
Secondary outcomes	
Onset and duration of RD	Time of onset and duration of post-radiation dermatitis
Toxicity in patients' irradiated skin	Common toxicity criteria of the cooperative group for skin suggested by the RTOG Foundation (https://www.rtog.org) [18]
Discomfort and pain concerning symptoms and signs related to dermatitis	Degree of skin discomfort caused by radiation. Subjective assessment and quantification by the patient on an ordinal scale (0 to 10) Pruritus, pain, itching or peeling of the skin
Quality of life	Quality of life of patients with skin conditions Skindex-29 questionnaire [21]