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Safety evaluation of a topical formulation containing microparticles of Chamomilla recutita (L.) Rauschert coated with chitosan

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Skin lesions are the target of nursing research and because of its impact on patients' life the prevention of these injuries is of great interest. In previous studies, a formulation to protect the skin against injuries was developed. However, before it can be applied for this purpose, a preliminary safety test is needed. Thus, the aim of this study was to evaluate the safety of a topical formulation containing microparticles of chamomile coated with chitosan on healthy volunteers' skin. It is an experimental, controlled and double blind study conducted with 35 volunteers. After approval of the Ethics Committee on Human Research of the Ribeirão Preto School of Nursing, participants applied the formulation with microparticles in a forearm and the same formulation without microparticles in the other forearm during four weeks. The evaluation was performed by objective measurements of erythema, melanin, and skin pH using biophysical skin techniques and also was evaluate to burning, itching, heat and pain. The results showed a slight increase in erythema in all skin areas evaluated. The amount of melanin decreased slightly in the area of formulation application. There was a pH increase in all skin areas evaluated. Regarding the subjective parameters of pain, burning, itching and heat only one participant at the end of the evaluation reported mild pain sensation on the area where the microparticle formulation was applied, which was rapidly, alleviated a few minutes after application. There was no change in evaluation of discoloration and edema parameters. We can conclude that the formulation is safe for skin application. In addition, more studies involving prevention of skin injuries will be carried out.

Biography

Cristina Mara Zamarioli has	completed her	r undergraduation	n course and	Master's degre	e from the l	Jniversity of São	Paulo at Ribeira	io Preto College	of Nursing
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