Q

Healio > News > Dermatology > Practice Management

American Society for Dermatologic Surgery



By Earl Holland Jr.

Source/Disclosures

Source: Palm M, et al. A randomized, evaluator-blinded, multi-center study to evaluate safety and effectiveness of a biostimulatory polyt-lactic acid injectable implant after changes in reconstitution. Presented at:
American Society for Dermatologic Surgery annual meeting; Oct 9-11, 2020 (virtual meeting).

Disclosures: This study was sponsored by Galderma R&D, LLC.





Changes in reconstitution of PLLA for nasolabial folds did not affect safety



A regimen of <u>poly-L-lactic acid and lidocaine</u> did not compromise safety in the treatment of nasolabial folds, according to findings presented at the American Society for Dermatologic Surgery annual meeting.

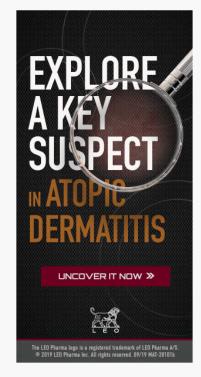
Melanie Palm, MD, MBA, medical director at Art of Skin MD in Solana Beach, California, and colleagues evaluated the safety and efficacy of a biostimulatory poly-L-lactic acid (PLLA) injectable implant to correct nasolabial folds after changes in reconstitution and injection procedures compared with the U.S. label.

The researchers analyzed data from a 48-week, randomized, evaluator-masked, multicenter study in which subjects received a single treatment regimen comprised of four injection sessions. PLLA was reconstituted with either 8 mL or 5 mL sterile water for injection, and the 8 mL solution included 1 mL of 2% lidocaine.

A wrinkle assessment scale (WAS) was used to evaluate the primary endpoint of change from baseline of <u>both</u> nasolabial folds at week 48.

Fifty-nine subjects were in the 8 mL group and 21 in the 5 mL group. The subjects were 95% women and had a mean age of 51.5 years.

Both groups had high WAS responder rates, consisting of an improvement of at least one grade from baseline, at week 24 (75%) and week 48 (67%), which met the primary effectiveness endpoint. Aesthetic improvement was rated as high (86%).





N95 masks may lead to greater adverse skin reactions

Adverse events, mostly mild and transient, were reported by 33% of subjects in the 5 mL group and 12% in the 8 mL group.

"PLLA was effective for treatment of nasolabial folds, and safety was not compromised using a higher reconstitution volume including lidocaine, administered immediately after reconstitution," the researchers wrote.

Related Content



American Society for Dermatologic Surgery



American Academy of Dermatology Meeting A phase 1, randomized, controlled clinical study of CC-11050 in people living with HIV with suppressed plasma viremia on antiretroviral therapy (APHRODITE)

Afroditi Boulougoura et al., J Immunol, 2019

Phil Szuromi, Science, 2016

GenomeWeb, 2011

Probiotic strains detect and suppress cholera in mice

Ning Mao et al., Sci Transl Med, 2018

Powered by TREND MD

Follow Healio ♥ f in ふ

Tell us what you think about Healio.com $\,\,>\,\,$

Help

Sign Up for Email Get the latest news and education delivered to your inbox Email address Specialty All Specialties

Account Information My Saved	Healio.com About Healio
Log Out	Feedback
Update Publication Mailing Address	Healio Network
Subscribe	Publications
My Account	Contact the News Desk
Email Subscriptions and Alerts	Contact Us
Institutional and Library Subscriptions	About the Wyanoke Grou
Help	Healio Jobs ☑
	Advertising Information
	Reprints
	Sitemap

©2020 Healio All Rights Reserved.

Legal Medical Disclaimer Privacy Policy Do Not Sell My Personal Information Editorial Policy and Philosophy Terms and Conditions Permissions