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Abstract	
<b>Background:</b> The efficacy of photodynamic therapy (PDT) using topical 5-aminolevulinic acid (ALA) for the treatment of actinic keratosis (AKs) is lower on the distal extremities compared with the head and neck areas. The strong temperature dependence of porphyrin synthesis in biologic tissue	PAGE NAVIGATION
suggests that heating skin during incubation may improve the efficacy of PDT, particularly in areas where biologic temperatures are naturally lower. The aim of this study was to evaluate the efficacy	Title & authors
and tolerability of temperature-modulated PDT for the treatment of AKs on the extremities.  Methods: In this IRB-approved, single-center study, the upper or lower extremities of 20 subjects	
were treated with 20% ALA under occlusion, followed by 10 J/cm, 417-nm blue light. One of the 2 extremities treated was heated during the 1-hour incubation. Outcome measures included lesion	Similar articles
counts, tolerability, and global improvement at baseline, 1 week, and 2 and 6 months after treatment. <b>Results:</b> The median temperatures of the heated and control sides were 38.8°C and 29.4°C,	MeSH terms
respectively. The median clearance for the heated side was significantly greater than the control side at 2 and 6 months (p < .0001). Typical PDT side effects were greater on the heated side compared with the control yet were well tolerated by all subjects.	Substances
<b>Conclusion:</b> Warming the skin during incubation of ALA seems to improve the efficacy of PDT in the	Related information
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A multicenter, randomized, vehicle-controlled phase 2 study of blue light photodynamic therapy with aminolevulinic acid HCl 20% topical solution for the treatment of actinic keratoses on the upper extremities: the effect of occlusion during the drug incubation period. Schmieder GJ, Huang EY, Jarratt M. J Drugs Dermatol. 2012 Dec:11(12):1483-9. PMID: 23377520 Clinical Trial.	
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Gilaberte Y, Aguilar M, Almagro M, Correia O, Guillén C, Harto A, Pérez-García B, Pérez-Pérez L, Redondo P, Sánchez-Carpintero I, Serra-Guillén C, Valladares LM. Actas Dermosifiliogr. 2015 Oct;106(8):623-31. doi: 10.1016/j.ad.2015.06.001. Epub 2015 Jun 24. PMID: 26115793 English, Spanish.

Current treatments of actinic keratosis. Gold MH, Nestor MS. J Drugs Dermatol. 2006 Feb;5(2 Suppl):17-25. PMID: 16485877 Review.

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#### Cited by 8 articles

Comparison of Blue and White Lamp Light with Sunlight for Daylight-Mediated, 5-ALA Photodynamic Therapy, in vivo. Marra K. LaRochelle EP, Chapman MS, Hoopes PJ, Lukovits K, Maytin EV, Hasan T, Pogue BW. Photochem Photobiol. 2018 Sep;94(5):1049-1057. doi: 10.1111/php.12923. Epub 2018 May 16. PMID: 29663426 Free PMC article.

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Fisher CJ, Niu C, Foltz W, Chen Y, Sidorova-Darmos E, Eubanks JH, Lilge L. PLoS One. 2017 Jul 31;12(7):e0181654. doi: 10.1371/journal.pone.0181654. eCollection 2017. PMID: 28759636 Free PMC article.

#### Photodynamic therapy in dermatology beyond non-melanoma cancer: An update. Wen X. Li Y. Hamblin MR.

Photodiagnosis Photodyn Ther. 2017 Sep;19:140-152. doi: 10.1016/j.pdpdt.2017.06.010. Epub 2017 Jun 21. PMID: 28647616 Free PMC article. Review.

# Effect of Expedited Microneedle-Assisted Photodynamic Therapy for Field Treatment of Actinic Keratoses: A Randomized Clinical Trial.

Petukhova TA, Hassoun LA, Foolad N, Barath M, Sivamani RK. JAMA Dermatol. 2017 Jul 1;153(7):637-643. doi: 10.1001/jamadermatol.2017.0849. PMID: 28514458 Free PMC article. Clinical Trial.

#### Current Advances in 5-Aminolevulinic Acid Mediated Photodynamic Therapy.

 Thunshelle C, Yin R, Chen Q, Hamblin MR.

 Curr Dermatol Rep. 2016 Sep;5(3):179-190. doi: 10.1007/s13671-016-0154-5. Epub 2016 Jul 13.

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#### MeSH terms

- > Aged
- > Aged, 80 and over
- > Aminolevulinic Acid / therapeutic use\*
- > Blister / etiology
- > Clinical Protocols
- > Erythema / etiology
- > Extremities
- > Female
- > Humans
- > Keratosis, Actinic / drug therapy\*
- > Male

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> Treatment Outcome

## Substances

> Photosensitizing Agents

> Aminolevulinic Acid

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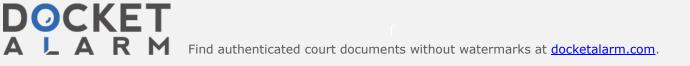
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Dermatol Surg. 2014 Oct;40(10):1094-102. doi: 10.1097/01.DSS.0000452662.69539.57. PMID: 25207759

- Comparison of Blue and White Lamp Light with Sunlight for Daylight-Mediated, 5-ALA Photodynamic Therapy, in vivo. Marra K, LaRochelle EP, Chapman MS, Hoopes PJ, Lukovits K, Maytin EV, Hasan T, Pogue BW.
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   PMID: 28163981 Free PMC article.
- 7 In-office Painless Aminolevulinic Acid Photodynamic Therapy: A Proof of Concept Study and Clinical Experience in More Than 100 Patients. Martin GM.

J Clin Aesthet Dermatol. 2016 Feb;9(2):19-26. PMID: 27047629 Free PMC article.

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- Comprehensive analytical model for CW laser induced heat in turbid media.
   Erkol H, Nouizi F, Luk A, Unlu MB, Gulsen G.
   Opt Express. 2015 Nov 30;23(24):31069-84. doi: 10.1364/OE.23.031069.
   PMID: 26698736 Free PMC article.
- Pre-treatment protoporphyrin IX concentration in actinic keratosis lesions may be a predictive biomarker of response to aminolevulinic-acid based photodynamic therapy.
   Kanick SC, Davis SC, Zhao Y, Sheehan KL, Hasan T, Maytin EV, Pogue BW, Chapman MS.

Photodiagnosis Photodyn Ther. 2015 Dec;12(4):561-6. doi: 10.1016/j.pdpdt.2015.10.006. Epub 2015 Oct 22. PMID: 26480810 Free PMC article. Clinical Trial.

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