A PILOT STUDY TO ASSESS THE EFFICACY AND TOLERABILITY OF TWO NEW PROPRIETARY, PURE HYPOCHLOROUS ACID-BASED (HOCL) TREATMENTS FOR MILD-TO-MODERATE ACNE VULGARIS

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BACKGROUND

Hypochlorous acid (HOCl) has been shown to have antiinflammatory properties and immediate bactericidal activity against Propionibacterium acne. Clinically, HOCl has been shown to be an effective topical treatment for acne vulgaris. New formulations of HOCl (Microcyn® Technology, IntraDerm™ Pharmaceuticals, a Division of Sonoma Pharmaceuticals. Recent successful studies support further development of these products).

The following pilot study was performed to assess the efficacy and tolerability of a HOCl-based solution and gel for the treatment of subjects with mild-to-moderate acne vulgaris.

Efficacy was assessed by acne lesion count. Tolerability was based on subject global assessment (SGA) of tolerability, daily diaries, local skin reactions (LSRs) and adverse events.

METHODS

Subjects
Male or female subjects (N=20) 12 to 40 years old with mild-to-moderate facial acne vulgaris defined as 10-90 noninflammatory lesions and 10-50 inflammatory lesions with no nodules or cysts.

Procedures
Subjects were randomized 1:1 to receive monotherapy with HOCl-based liquid or gel formulation and instructed to apply their assigned product twice-daily using cotton pads.

Subjects attended six biweekly office visits for 12 weeks. Assessments during each visit included acne lesion counts, LSR values, digital images, review of daily diaries and adverse event assessments. Porphyrin counts were obtained as a measure of skin bacteria present (VISIA® Complexion Analysis, Canfield Scientific).

RESULTS

The study was completed by 16 subjects. By week 12, use of HOCl solution resulted in a significant decrease in inflammatory (68%; p=0.0002) and noninflammatory lesions (43%; p=0.0025) (Figure 1). The HOCl gel also produced a significant decrease in inflammatory (64%; p=0.0031) and noninflammatory lesions (43%; p=0.0054) (Figure 2). There was no significant decrease in porphyrin counts.

CONCLUSION

This study adhered to the Declaration of Helsinki, International Conference on Harmonisation Good Clinical Practice and US Code of Federal Regulations. The protocol was approved by a commercial IRB and informed consent was obtained from each subject.

REFERENCES


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