International Journal of Research and Review
[Indexed, Peer-Reviewed Journal]
Volume 13; Issue: 7; July 2026
Website: www.ijrrjournal.com
Research Paper *E-ISSN: 2349-9788; P-ISSN: 2454-2237*

Clinical Evaluation of EqualsTwo® Anti-Stretch Mark Oil in Pregnant and Lactating Women: A Prospective Open-Label Study

Dhruv Zaveri[1], Trupti Patel[2], Kinjal Barot[1], Jaimin Vaishnav[1], Parth Joshi[3], Simran Sathi[3], Sunil S. Iyer[4], M. E. Kannan[5]

[1]Biopharmaceutics and Clinical Development, Zydus Lifesciences Limited, Pharmaceutical Technology Centre (PTC), Sarkhej Bavla N.H. No.8A, Moraiya, Tal: Sanand, Dist.: Ahmedabad 382 210, Gujarat, India,
[2]Zydus Wellness Centre, Ahmedabad 382481, Gujarat, India.
[3]Cliantha Research Limited, TP 86, FP 28/1, Off S.P. Ring Road, Sarkhej, Ahmedabad – 382210
[4] Head, Biopharmaceutics and Clinical Development, Zydus Lifesciences Limited, Sarkhej Bavla N.H. No.8A, Moraiya, Tal: Sanand, Dist.: Ahmedabad 382210, Gujarat, India,
[5] Head, Pharmaceutical Technology Centre (PTC), Zydus Lifesciences Limited, Sarkhej Bavla N.H. No.8A, Moraiya, Tal: Sanand, Dist.: Ahmedabad 382210, Gujarat, India.

Corresponding Author: Dhruv Zaveri

DOI: https://doi.org/10.52403/ijhsr.20260713

ABSTRACT

Introduction: Striae gravidarum, or stretch marks of pregnancy, are a common cutaneous physiological change occurring during pregnancy.
Objectives: This study investigates the safety and efficacy of EqualsTwo® Anti-Stretch Mark Oil (investigation product) in reducing and preventing stretch marks in pregnant (1st and 2nd trimester) and lactating women (up to 3 months postpartum).
Methods: An open-label, single-arm, prospective study enrolled 60 healthy female participants (25 pregnant in the first/second trimester, 35 lactating up to 3 months postpartum), with 41 completing the trial. Participants applied the investigation product twice daily for 60 days. Efficacy and safety were assessed using clinical scar grading scales (POSAS, VSS, Goodman & Baron), instrumental measurements (Cutometer®, Digital Vernier Calipers), and patient satisfaction surveys at baseline, day 15, day 30, and day 60.
Results: By the end of the study, abdominal scar pigmentation and vascularity improved by 29% and 40.6%, respectively. Pliability, thickness, and relief each improved by over 23%. All participants reported complete resolution of scar-related pain, pruritus, irregularity, discoloration, and stiffness. Instrumental analysis showed an increase in skin elasticity (2.7%), in firmness (2.4%), and reduction in scar size (30.5%) ($p < 0.0001$). No adverse events occurred, and, with participants describing the investigation product as easy to use, non-sticky, fast-absorbing, and pleasantly scented.
Conclusion: EqualsTwo® Anti-Stretch Mark Oil (Investigation product), a plant-based topical, significantly improved striae gravidarum and enhanced skin elasticity and firmness over 60 days in pregnant and lactating women. It was well tolerated with no adverse effects, supporting its safety and efficacy for pregnancy-related dermal changes.
Keywords: Maternal skincare, Postpartum skin health, Striae gravidarum, Skin elasticity, Topical botanical oils.

INTRODUCTION

Striae gravidarum (SG), commonly referred to as stretch marks of pregnancy, are a frequent dermatological concern encountered during pregnancy and postpartum periods. These linear dermal scars arise due to skin stretching and hormonal alterations that disrupt collagen and elastin networks, most commonly appearing on the abdomen, breasts, thighs, and buttocks during the second and third trimesters.[1, 2] Globally, the prevalence of SG ranges from 50% to 90% among pregnant women, depending on ethnicity, genetic predisposition, and maternal age.[3, 4] In the Indian context, a cross-sectional study by Nandi and Choudhury reported a prevalence of 80.78% among primigravida women in the third trimester.[5]

Despite their benign nature, striae can significantly impact psychological well-being, self-esteem, and body image, particularly among primigravida women.[6] The pathophysiology of striae involves a combination of mechanical stress and hormonal influences especially elevated glucocorticoids which lead to fibroblast dysfunction, reduced collagen synthesis, and localized dermal tearing.[7] Histologically, affected skin reveals epidermal atrophy, disrupted collagen fibrils, and elastolysis, which collectively compromise skin elasticity and tensile strength.[8]

Numerous topical agents have been employed to prevent or minimize the appearance of SG, including emollients, herbal creams, and oil-based formulations. Among these, botanical oils such as sweet almond oil and sesame oil have gained popularity due to their natural origin, antioxidant properties, and ease of application. [9–11] However, clinical evidence supporting their efficacy remains inconclusive. Randomized controlled trials have reported mixed outcomes: some studies show significant reductions in striae incidence or severity with sesame and almond oil,[10] while others demonstrate no difference compared to placebo. [12, 13] Furthermore, large-scale reviews, including a Cochrane systematic review, conclude that there is insufficient high-quality evidence to recommend any specific topical treatment for stretch mark prevention during pregnancy.[14]

While the majority of oil-based products are considered safe for dermal use in pregnancy, rare concerns have been raised regarding potential adverse effects. For instance, a study reported an increased risk of preterm birth associated with frequent topical use of almond oil, possibly due to prostaglandin-related uterine activity.[15] Nevertheless, this finding has not been corroborated by controlled trials, which report high user acceptability and minimal side effects.[11, 12] Given the high prevalence of SG and the widespread use of oil-based products among expectant and new mothers, there is a clear need for well-designed clinical studies that assess both the efficacy and safety of such formulations. EqualsTwo® Anti-Stretch Mark Oil (investigation product) is a novel, plant-oil-based formulation developed to address this gap. It contains swertiamarin, a phytochemical known for its anti-inflammatory and antioxidant activity, which may aid in dermal regeneration and reduction of pigmentation.[16] Coconut oil, rich in lauric acid, supports skin barrier repair while providing deep moisturization and antimicrobial protection.[17] Sesame oil enhances skin elasticity and offers emollient and antioxidant effects that may reduce the formation of stretch marks. Flaxseed oil, a potent source of omega-3 fatty acids, helps improve skin hydration, elasticity, and texture.[18] Oat oil contains avenanthramides and lipids that soothe irritation, strengthen the skin barrier, and contribute to overall skin smoothness and comfort.[19] Despite widespread use of topical oils during pregnancy, evidence from well-designed clinical studies remains inconclusive. This study aimed to evaluate the clinical effectiveness and safety of a plant-based topical oil formulation in pregnant and lactating women with striae gravidarum.

MATERIALS & METHODS

Study Design and Setting

This was an open-label, single-arm, prospective clinical study designed to evaluate the efficacy and safety of the investigation product in the management and prevention of SG, as well as improvement of skin elasticity and firmness in pregnant and lactating women. The study was conducted at Cliantha Research, Ahmedabad, an independent clinical research organization (CRO).

Participants

A total of 60 healthy female subjects, aged 22–40 years, were enrolled: 25 Pregnant women who were primipara, first or second trimester, confirmed by a gynecologist and 35 lactating women, within 42 weeks postpartum, with healthy, full-term infants aged up to 3 months and no congenital abnormalities; out of which 41 participants completed the study. All participants which were included had visible abdominal stretch marks, were in good general health, and had no history of systemic dermatologic conditions as confirmed over physical examination at the site. Patient consent was taken from all the patients in their understandable vernacular language before initiating study.

Product Usage Instructions

The formulation consisted of plant-derived oils aimed at enhancing skin hydration, promoting collagen synthesis, and supporting scar remodeling. All participants were instructed to apply the investigation product twice daily on the abdominal area for a continuous period of 60 days.

Outcome Measures

The primary outcomes focused on both clinical and instrumental assessments. Reduction in the severity of abdominal scars was evaluated using the Patient and Observer Scar Assessment Scale (POSAS) and the Vancouver Scar Scale (VSS) on Days 1, 15, 30, and 60. The Goodman and Baron qualitative scar scale was also used to assess changes in scar morphology. Improvement in skin elasticity and firmness was assessed using a Cutometer®, and scar dimension analysis with Digital Vernier Calipers at the same time point at the study site by the physician.

Secondary outcomes included participant-reported perceived changes in scar-related and skin-quality parameters, and product usability/acceptability over time. Subjective assessments were captured using a Self-Assessment Questionnaire administered on Days 15, 30, and 60, covering perceived improvements in scar appearance, skin tone, hydration, elasticity, and comfort. Product acceptability was evaluated using a Product Response Index assessing ease of application, absorption characteristics, sensory attributes, and overall satisfaction.

Safety outcomes:

Participants were monitored throughout the study for any adverse dermatologic events, including erythema, edema, rash, dryness, itching, or irritation.

Ethical Considerations

The study was approved by the Om Institutional Ethics Committee and conducted in accordance with the ethical principles outlined in the Declaration of Helsinki and the Good Clinical Practice (GCP) guidelines. The trial was registered with the Clinical Trials Registry – India (CTRI/2022/08/044605) prior to patient enrolment.

Statistical Analysis

Descriptive statistics were computed for all variables. The Wilcoxon Signed Rank Test was used to evaluate changes in POSAS, VSS, and Goodman & Baron scores, as well as in Cutometer and caliper-based measurements, across different time points. For normally distributed parameters, paired t-tests were applied. A p-value < 0.05 was considered statistically significant.

RESULT

The mean age of participants was 28.9 years (SD = 4.60), ranging between 22 and 37 years, indicating a relatively young and homogenous study population. (Table 1)

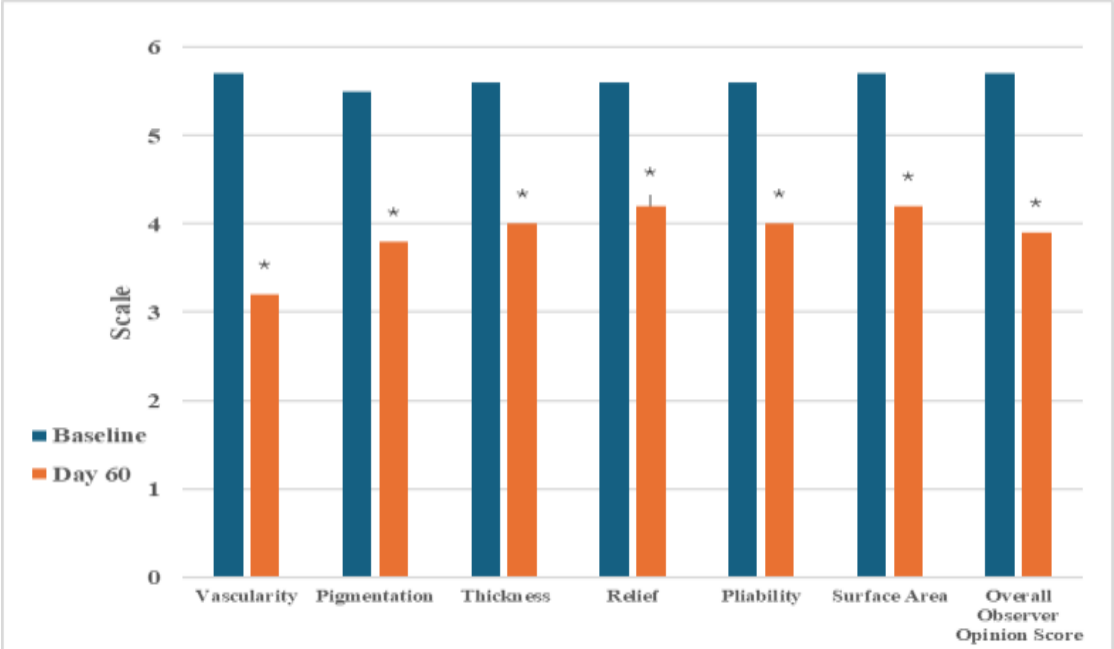
Table 1: Summary of demographic characteristics of the study participant

Variables	
Gender, n (%)	
Female	60 (100%)
Age (Years)	
Mean (SD)	28.9 (4.60)
Median	29.0
Min, Max	22, 37

Primary Outcomes:

Dermatological Assessment

Significant improvements were observed in all scar characteristics by Day 60, as assessed by the POSAS (Observer Component). The most notable reductions were in vascularity (−40.6%), overall observer opinion (−30.5%), and pigmentation (−29.0%). All changes were statistically significant ($p < 0.0001$). (Figure 1)



Parameter	Vascularity	Pigmentation	Thickness	Relief	Pliability	Surface Area	Overall Observer Opinion Score
%change	40.60	29.00	26.50	23.80	27.40	25.30	30.50

Figure 1. Improvement in all POSAS observer-assessed scar parameters at Day 60 versus baseline

Instrumental Analysis

Objective instrumental evaluations demonstrated progressive improvements across all measured parameters. Scar size reduced by 30.5%, skin elasticity increased by 2.7%, and firmness by 2.4% over 60 days (Table 2).

Table 2. Instrumental and Subjective Outcomes Over 60 Days of Product Use

Assessment Parameter	Baseline (Mean ± SD)	Day 60 (Mean ± SD)	% Change	p-value
Scar Size (mm)	6.70 ± 1.30	4.61 ± 0.76	−30.5%	< 0.0001
Skin Elasticity (Cutometer)	0.388 ± 0.019	0.399 ± 0.019	+2.73%	< 0.0001
Skin Firmness (Cutometer)	0.386 ± 0.019	0.376 ± 0.019	−2.42%	< 0.0001

Skin firmness was assessed using a Cutometer, which measures skin elasticity and firmness by applying controlled suction and recording deformation, providing objective, reproducible biomechanical data.

All parameters showed statistically significant change from baseline. Progressive changes in skin biomechanics and scar size over time are detailed in Table 3.

Table 3. Progressive Changes in Instrumental Parameters Over 60 Days

Timepoint	Skin Elasticity	Skin Firmness	Scar Size
Day 15	+0.8%	+0.8%	−6.3%
Day 30	+1.7%	+1.6%	−16.0%
Day 60	+2.7%	+2.4%	−30.5%

Additionally, the Goodman & Baron scale showed a 32.5% improvement, and the VSS improved by 23.7%. (Figure 2)

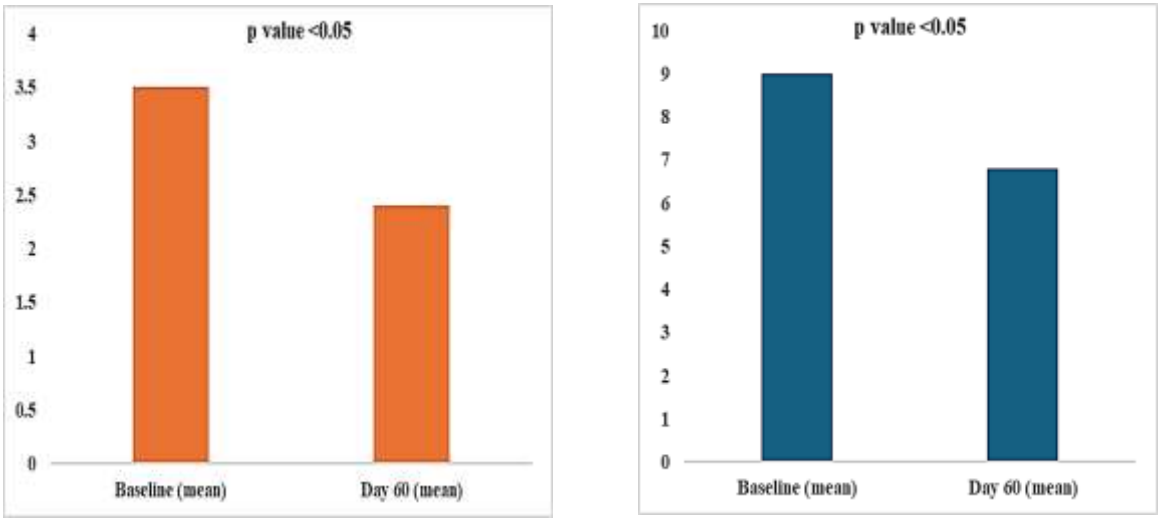


Figure 2: (a) Improvement in Goodman & Baron Scale score and (b) Vancouver Scar Scale (VSS) Score from Baseline to Day 60Secondary outcomes.

Skin firmness was assessed using a Cutometer, which measures skin elasticity and firmness by applying controlled suction and recording deformation, providing objective, reproducible biomechanical data.

Patient Self-Assessment and Product Perception

Self-reported outcomes using the POSAS – Patient Component confirmed marked symptomatic relief (Figure 3).

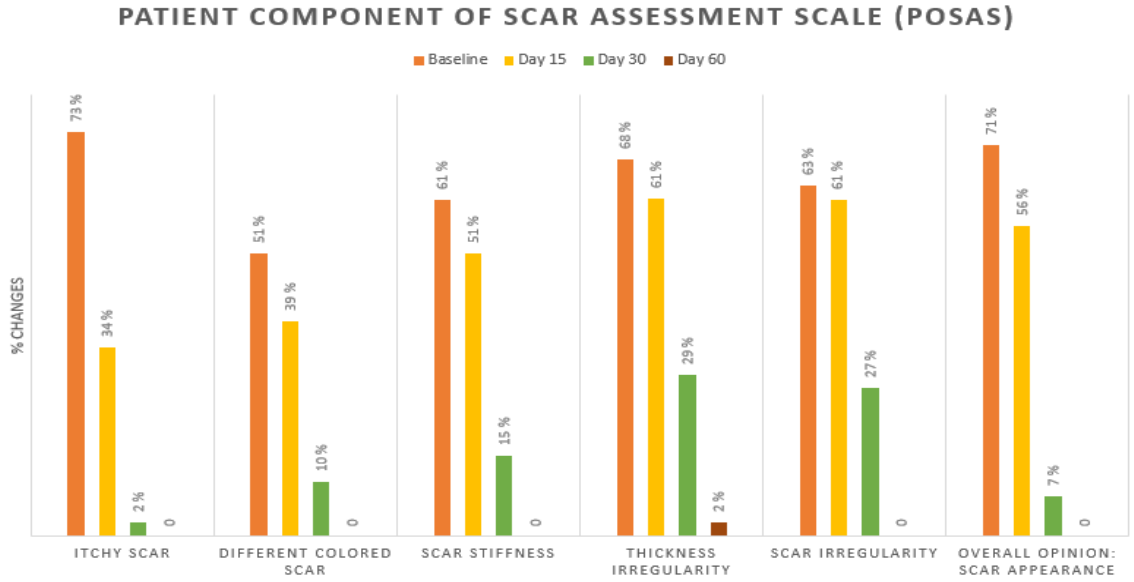


Figure 3: Self-Reported Scar Symptoms over time.

Itchiness, stiffness, different color of scars, scar irregularity and overall opinion on scar appearance dropped to 0% by Day 60, and only 2.4% reported any residual abnormal scar thickness.

In terms of product experience, the majority (>95%) of participants reported satisfaction with the investigation product. The product was easy to apply, quickly absorbed, non-greasy, and compatible with their skin type.

Safety outcomes

The product was well tolerated, and no adverse reactions or hypersensitivity events were reported during the study period. No adverse events or hypersensitivity reactions were reported throughout the study period.

DISCUSSION

Among the most pronounced outcomes, vascularity decreased by 40.6%, overall observer opinion rating improved by 30.5%, and pigmentation was reduced by 29.0%, all with p value less than 0.0001). These effects were also reflected in other scar features such as thickness (−26.5%), relief (−23.8%), pliability (−27.4%), and affected surface area (−25.3%). Instrumental data revealed a 30.5% reduction in scar size, 2.73% increase in skin elasticity, and a 32.5% improvement in scar quality as per the Goodman & Baron qualitative scale.

Dai et al. (2021) reported that with increasing SG severity, there was a progressive loss of skin elasticity (mean elasticity 0.86 in mild SG vs. 0.79 in severe cases), accompanied by an increase in average width of lesions (2.89 mm to 4.31 mm) and distribution area (0.15 to 0.48).[20] Compared to their results, our intervention effectively reversed these structural changes, scar width was reduced by over 30%, and elasticity improved significantly. The investigation product not only halts progression but may facilitate remodelling of the dermal matrix, reversing biomechanical deterioration associated with SG.

In this study, patient-reported discomforts such as itchiness and irregularity, which were initially reported by 73.2% and 70.7% of participants, respectively and were completely resolved by end of study. These findings are notable when considered alongside those of Yamaguchi et al. (2012), who reported that severe SG significantly worsened dermatology-specific quality of life in Japanese women, particularly in the emotional domain of the Skindex-29 ($p < 0.001$). Although Yamaguchi's study did not measure physical symptoms like itchiness, the resolution of these issues in our cohort may suggest a positive impact not just on skin condition but also on psychosocial well-being.[4]

In terms of prevalence and severity trends, Mammadov et al. (2024) observed that 31% of their participants exhibited severe SG (≥11 striae), with the abdomen being the most affected site (50.4%). While their study did not utilize standardized scoring systems like POSAS or VSS, the number and spread of striae were key indicators.[21] Our study adds value by quantifying scar evolution over time through validated tools, showing marked reduction across all measured parameters. These improvements in both scar dimensions and biomechanical attributes support the product's potential use even in populations with high SG prevalence and severity.

Furthermore, Dai et al. identified that elasticity dropped progressively with severity, and this mirrors the baseline characteristics in our cohort, where most participants had moderate to severe SG features.[20] However, with consistent use of the product, Cutometer® readings revealed a progressive 2.73% improvement in elasticity and a 2.42% increase in firmness at the end of study duration. These changes contrast the static or declining elasticity profiles observed in untreated or placebo-controlled cohorts.

The Goodman & Baron scar scale also revealed a 32.5% improvement in qualitative scar morphology in our

participants. This scale, while less commonly applied in SG research, offers a valuable adjunct perspective by capturing overall visual and textural improvements in the skin. No adverse events were reported, and the product demonstrated high cosmetic acceptability, with 100% of participants reporting ease of use, rapid absorption, pleasant fragrance, and overall satisfaction. The application of the investigation product over a 60-day period led to significant clinical improvements in both subjective symptoms and objective features of SG, including scar pigmentation, vascularity, pliability, thickness, and overall morphology. The intervention was associated with improvements in clinician- and patient-reported measures of striae gravidarum, consistent with literature linking SG severity to quality-of-life impact.

Limitation

Inference is limited by the single-arm open-label design, lack of a comparator, and short follow-up.

CONCLUSION

EqualsTwo® Anti-Stretch Mark Oil (Investigation product) demonstrated significant improvements in scar appearance, skin elasticity, and firmness were observed from day 15 of application, as demonstrated by both clinical assessments and instrumental measurements. It was found to be safe, well-tolerated, and clinically effective in reducing and preventing SG among pregnant and lactating women. High patient satisfaction and the absence of adverse effects further support its use as a topical intervention for managing pregnancy-related stretch marks.

Recommendation:

Larger, adequately powered randomized controlled trials with longer follow-up are needed to confirm efficacy and assess durability and clinical relevance.

Declaration by Authors

Ethical Approval: Approved

Acknowledgement: We would like to express our sincere appreciation and gratitude to Digicare Health Solutions Private Limited (DHSPL), for their significant contribution to the preparation of the manuscript and publication support.

Source of Funding: This study was funded by Zydus Life Sciences Limited.

Conflict of Interest: The authors declare that there is no financial conflict of interest with the content of this article. The study was funded by Zydus Lifesciences Ltd., who provided financial support for the study design, data collection, and analysis. However, the funding organization did not influence the data interpretation or the preparation of the manuscript. The authors declare that they have no personal or financial interests that could have influenced the conduct or reporting of this study.

REFERENCES

1. Salter SA, Kimball AB. Striae gravidarum. Clinics in dermatology. 2006 Mar 1;24(2):97-100.
2. Farahnik B, Park K, Kroumpouzos G, Murase J. Striae gravidarum: Risk factors, prevention, and management. Int J Womens Dermatol. 2016 Dec 6;3(2):77-85. doi: 10.1016/j.ijwd.2016.11.001.
3. Chang AL, Agredano YZ, Kimball AB. Risk factors associated with striae gravidarum. Journal of the American Academy of Dermatology. 2004 Dec 1;51(6):881-5.
4. Yamaguchi K, Suganuma N, Ohashi K. Quality of life evaluation in Japanese pregnant women with striae gravidarum: a cross-sectional study. BMC research notes. 2012 Aug 21;5(1):450.
5. Nandi N, Choudhury AP. Evaluation of prevalence and impact of striae gravidarum on the dermatology-specific quality of life in pregnant women. MedPulse–International Journal of Gynaecology. 2018 Jun;6:52-4.
6. Atwal GS, Manku LK, Griffiths CE, Polson DW. Striae gravidarum in primiparae. British Journal of Dermatology. 2006 Nov 1;155(5):965-9.
7. Watson, Parry, Humphries, Jones, Polson, Kielty, Griffiths. Fibrillin microfibrils are reduced in skin exhibiting striae distensae.

British Journal of Dermatology. 1998 Jun;138(6):931-7.
8. Elson ML. Treatment of striae distensae with topical tretinoin. The Journal of dermatologic surgery and oncology. 1990 Mar;16(3):267-70.
9. Cantelli M, Camela E, Marasca C, Fontanella G, Blasio C, Fabbrocini G. Topical oil formulation of plant extracts and vitamins as effective treatment for stretch marks and xerosis—An observational longitudinal study. Journal of Cosmetic Dermatology. 2021 Apr; 20:9-13.
10. Sadat Z, Saberi F, Babaei M, Bagheri A, Nasiri S. Comparison of the effect of sesame and almond oil on the incidence of striae gravidarum. Nursing and Midwifery Studies. 2020 Oct 1;9(4):208-14.
11. Hajhashemi M, Rafieian M, Rouhi Boroujeni HA, Miraj S, Memarian S, Keivani A, Haghollahi F. The effect of Aloe vera gel and sweet almond oil on striae gravidarum in nulliparous women. The Journal of Maternal-Fetal & Neonatal Medicine. 2018 Jul 3;31(13):1703-8.
12. Brennan M, Clarke M, Devane D. The use of anti stretch marks' products by women in pregnancy: a descriptive, cross-sectional survey. BMC pregnancy and childbirth. 2016 Sep 21;16(1):276.
13. Yu Y, Wu H, Yin H, Lu Q. Striae gravidarum and different modalities of therapy: a review and update. Journal of Dermatological Treatment. 2022 Apr 3;33(3):1243-51.
14. Brennan M, Young G, Devane D, Cochrane Pregnancy and Childbirth Group. Topical preparations for preventing stretch marks in pregnancy. Cochrane Database of Systematic Reviews. 1996 Sep 1;2012(11).
15. Facchinetti F, Pedrielli G, Benoni G, Joppi M, Verlato G, Dante G, Balduzzi S, Cuzzolin L. Herbal supplements in pregnancy: unexpected results from a multicentre study. Human reproduction. 2012 Nov 1;27(11):3161-7.
16. Vaijanathappa J, Badami S. Antiedematogenic and free radical scavenging activity of swertiamarin isolated from Enicostemma axillare. *Planta Med*. 2009;75(1):12-17. doi:10.1055/s-0028-1088333
17. Kim S, Jang JE, Kim J, Lee YI, Lee DW, Song SY, Lee JH. Enhanced barrier functions and anti-inflammatory effect of cultured coconut extract on human skin. Food and chemical toxicology. 2017 Aug 1; 106:367-75.
18. Al-Madhagy S, Ashmawy NS, Mamdouh A, Eldahshan OA, Farag MA. A comprehensive review of the health benefits of flaxseed oil in relation to its chemical composition and comparison with other omega-3-rich oils. European journal of medical research. 2023 Jul 18;28(1):240.
19. Sur R, Nigam A, Grote D, Liebel F, Southall MD. Avenanthramides, polyphenols from oats, exhibit anti-inflammatory and anti-itch activity. *Arch Dermatol Res*. 2008;300(10):569-574. doi:10.1007/s00403-008-0858-x
20. Dai H, Liu Y, Zhu Y, Yu Y, Meng L. Study on the methodology of striae gravidarum severity evaluation. Biomedical engineering online. 2021 Oct 25;20(1):109.
21. Mammadov B, Necipoğlu D, Vural G. Determination of Striae Gravidarum and its Affecting Factors During Pregnancy. Cyprus Journal of Medical Sciences. 2024 Feb 21.

How to cite this article: Dhruv Zaveri, Trupti Patel, Kinjal Barot, Jaimin Vaishnav, Parth Joshi, Simran Sathi et al. Clinical evaluation of EqualsTwo® anti-stretch mark oil in pregnant and lactating women: a prospective open-label study. *International Journal of Research and Review*. 2026; 13(7): 102-109.
DOI: *https://doi.org/10.52403/ijrr.20260713*

******