

POSTER

Non-inferiority trial comparing novel non-hormonal wound dressing to estrogen topical cream for treatment of Genitourinary Syndrome of Menopause

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INTRODUCTION

Genitourinary Syndrome of Menopause (GSM)^{1,2}

- Vaginal dryness
- Burning
- Dyspareunia (painful intercourse)
- Urinary discomfort in postmenopausal women

Current Treatment

Hormone-based treatments like Estrace vaginal cream are effective but may carry long-term side effects, highlighting the need for safer alternatives.³

StrataMGT

A non-hormonal, non-steroidal topical gel currently being investigated.

Aims to:

- Relieve GSM symptoms
- Support tissue recovery without the risks associated with hormonal therapies.³

Study Objective

Investigation of StrataMGT's potential to improve:

- Symptom management
- Patient outcomes
- Overall quality of life in women with GSM.

METHODS

This ongoing phase IV randomized, single-blinded, interventional study involves patients diagnosed with GSM, randomized 1:1 to receive either StrataMGT or Estrace.

Assessments

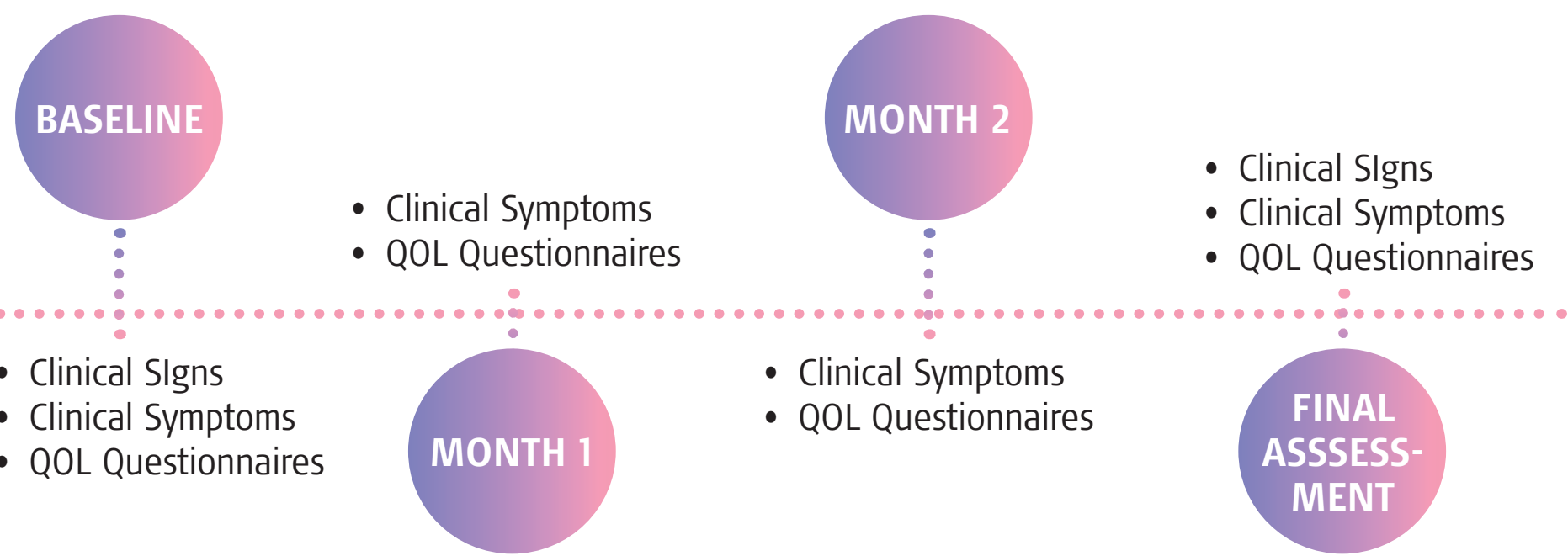


Figure 1: Schematic illustration of the study timeline.

Patient(s)

Enrolment goal: 100 female adults. Interim analysis presented included data from 25 patients: 12 using StrataMGT, 13 using Estrace.

Intervention(s)

Participants applied either StrataMGT daily for 3 months or Estrace vaginal cream daily for two weeks, then three times per week up to 3 months.

DISCUSSION

The interim results of this ongoing trial demonstrate **promising efficacy** and patient-reported outcomes for the non-hormonal silicone gel in managing GSM. Significant improvements were noted in key symptoms such as dyspareunia and dryness, alongside reductions in burning, stinging, and irritation, **improving overall quality of life**. Clinically, marked improvements in dryness and tissue thinning suggest the gel aids in hydration and mucosal protection.

Patient-reported outcomes (Table [1]) further support these findings, but also highlight StrataMGT consistently receiving higher scores across all domains, particularly in tolerability ($p = 0.039$), indicating better patient acceptance. Although other measures like ease of use and treatment satisfaction trended in favor of StrataMGT, these did not reach statistical significance, warranting further investigation. Overall, these results **highlight the potential of the silicone gel** as a **non-hormonal alternative for managing GSM**, with larger trials needed to confirm these findings.

INTERIM RESULTS

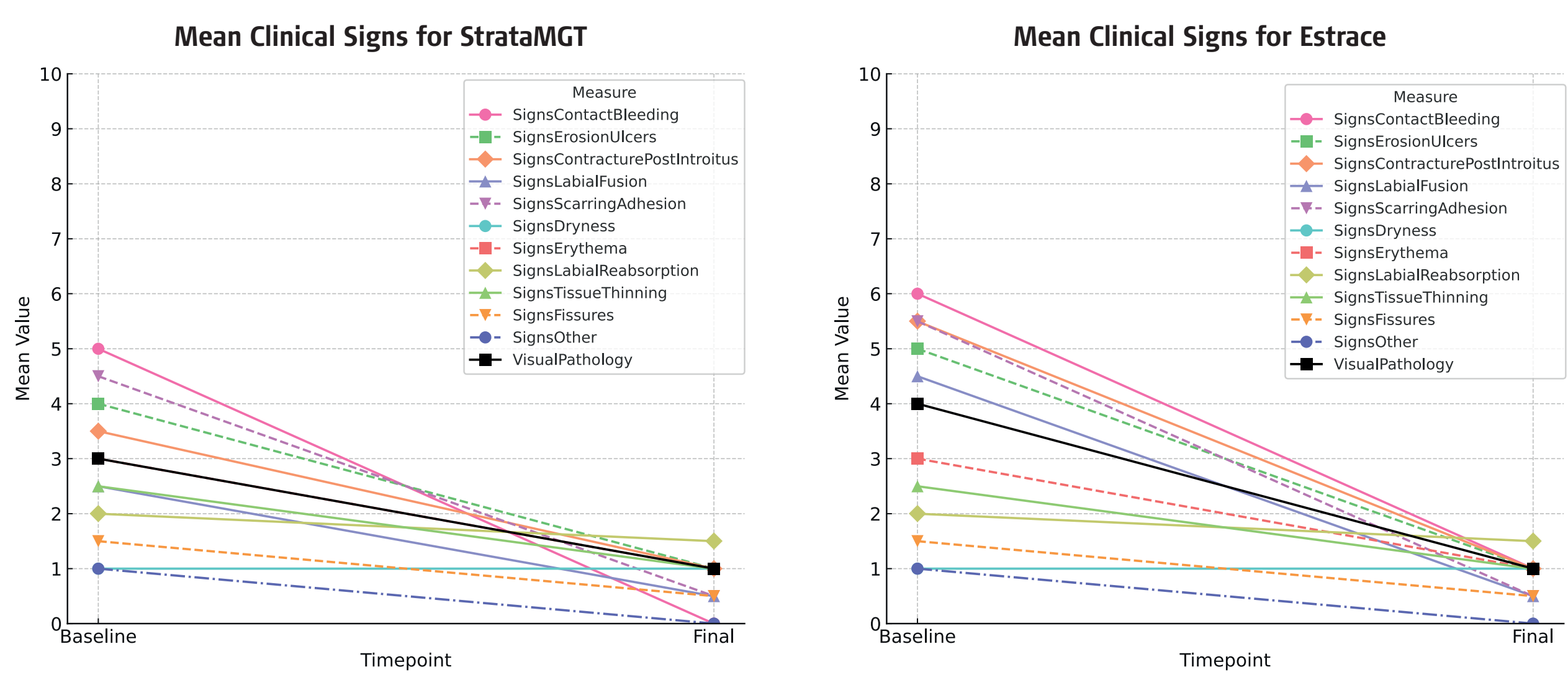


Figure 2: Regression of clinical signs during the study using Estrace. N = 13 patients.

Figure 3: Regression of clinical signs during the study using StrataMGT. N = 12 patients.

Clinical Signs and Symptoms: Notable improvements, decrease of intensity, in both clinical signs and symptoms of GSM.

Clinical signs: Visual pathology showed reduction

Estrace: mean improvement 2.37

StrataMGT: mean improvement 3.43

Clinical symptoms: Dyspareunia showed the greatest reduction

Estrace: mean improvement 3.62

StrataMGT: mean improvement 4.13

Patient-Reported Outcomes: Performance ratings (see Table 1) from patients consistently indicated higher scores for StrataMGT across all assessed domains, suggesting superior patient acceptance of the treatment.

Table 1: Product performance during the trial between 1 (lowest) – 5 (highest).

	Randomization Group	N	Mean	Std. Deviation	Std. Error Mean	Significance
Tolerability	Estrace	12	3.4167	1.31137	.37856	0.039*
	StrataMGT	13	4.3846	.76795	.21299	
Ease of use	Estrace	12	3.7500	1.21543	.35086	0.139
	StrataMGT	13	4.3846	.76795	.21299	
Treatment satisfaction	Estrace	12	3.5833	1.44338	.41667	0.147
	StrataMGT	13	4.3846	1.19293	.33086	
Feel on the skin	Estrace	12	3.1667	1.26730	.36584	0.071
	StrataMGT	13	4.0769	1.11516	.30929	

CONCLUSION

This study plays an important role in the advancement of GSM treatment, showing decreasing of symptoms at an interim state already.

1. Castelo-Branco C, Cancelo MJ, Villero J, Nohales F, Juliá MD. Management of post-menopausal vaginal atrophy and atrophic vaginitis. *Maturitas*. 2005;52:46-52. doi:10.1016/j.maturitas.2005.06.014 2. Angelou, K. et al. (2020). *Cureus*, 12(4), e7586. https://doi.org/10.7759/cureus.7586y. 3. Hall, P. (2024). A Feasibility study investigating a topical preparation as novel adjunct treatment for the symptomatic management of vulvovaginal skin conditions. *Womens Health Reports*, 5(1), 444–452. https://doi.org/10.1089/whr.2024.0026