

Patient Recruitment and Barriers to Enrollment in a Postoperative Pain Clinical Trial: Findings from the KALPAS Study

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INTRODUCTION

- Patient enrollment is essential for clinical trial success, yet participation is often limited by financial, logistical, and safety-related concerns.¹
- In anesthesia research, additional barriers include fear of adverse effects, perceived loss of control, and procedural burden.²
- The ketamine analgesia for long lasting pain relief after surgery (KALPAS) trial implemented mitigation strategies, such as participant compensation, standardized educational materials, and flexible consent and follow-up, to reduce these barriers.
- This analysis evaluates the effectiveness of these strategies and identifies remaining obstacles to enrollment.

METHODS

Design: Ongoing, multicenter, phase 3, double-blind trial testing ketamine for prevention of post-mastectomy pain syndrome

Sites: 16 institutions across the U.S., including NYU Langone, Brigham and Women’s, Mayo Clinic, MD Anderson, and others

Eligibility: Women 18 and older scheduled for mastectomy for oncologic indication

Recruitment period: Sept 2021 – Mar 2025

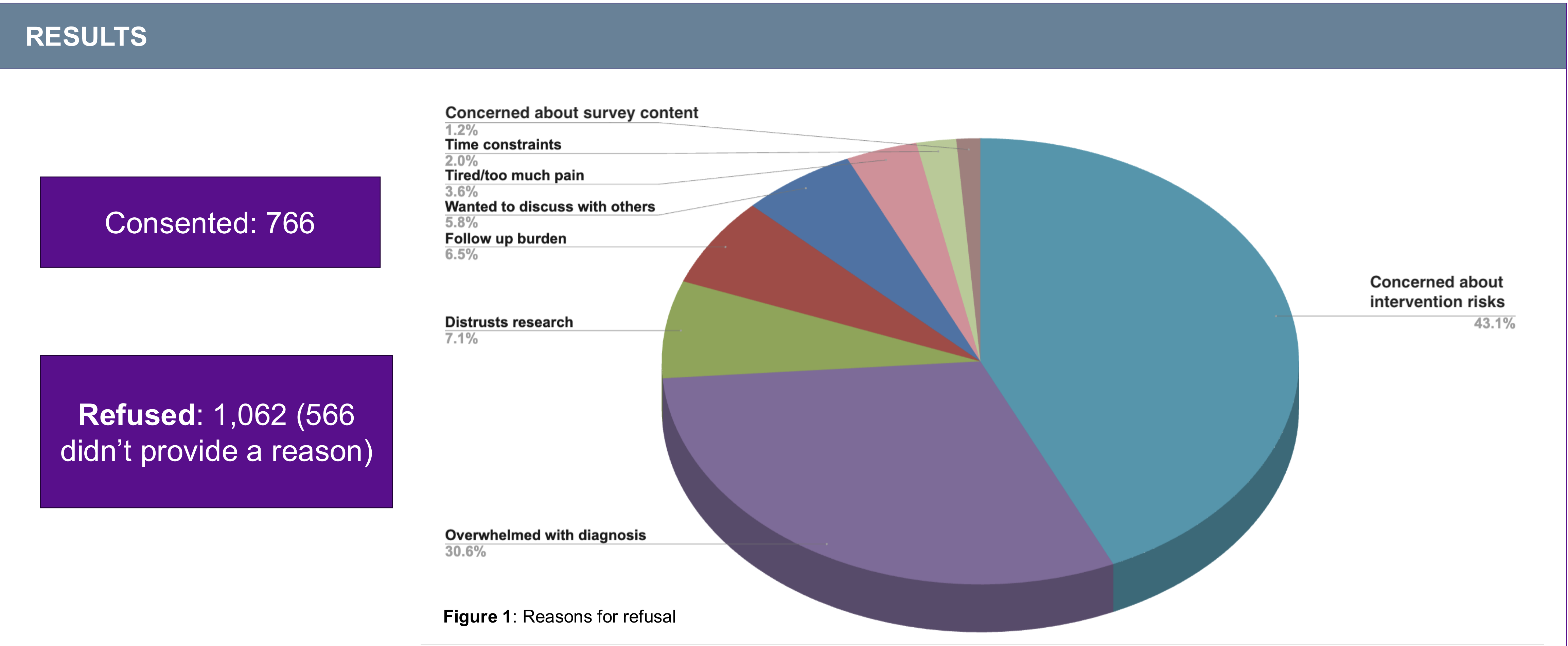
Recruitment strategy:

- Education (website, brochures, phone calls)
- Compensation
- Flexible consent and survey options (in-person or electronic)

Screened: 2,449 patients

Approached: 1,828 patients

Outcomes measured: Consent vs refusal; reasons for refusal



DISCUSSION

The KALPAS trial achieved a 41.9% enrollment rate, which is higher than what is commonly reported in anesthesia clinical trials.³

Effective strategies:

- Clear education on ketamine safety helped manage concerns
- Electronic consent increased flexibility and allowed patients to review materials on their own time

Remaining barriers:

- Ongoing concerns about treatment risk
- Patients feeling overwhelmed by diagnosis and upcoming surgery

Limitations:

- Over half of patients who refused did not provide a reason
- Findings may not generalize outside the mastectomy population

Future directions:

- Improve collection of refusal reasons (brief surveys, digital prompts, follow-ups)
- Develop targeted strategies addressing risk concerns and patient burden

PROMOTIONAL MATERIALS

Why is this study important?

- Long-term pain or discomfort after a mastectomy may occur.
- The KALPAS Study is one of very few studies ever done to treat and prevent women’s chronic pain after a mastectomy.
- KALPAS is part of the National Institutes of Health (NIH) HEAL Initiative, a national effort to find science-based solutions to the opioid crisis in the U.S.

Taking part in the KALPAS Study is up to you. If you join, you can leave the study at any time.

How can I learn more about the KALPAS Study?

Please contact your local study coordinator:

Raven Perez
1(347) 387- 5109
kalpas@nyulangone.org

or visit us at:
www.KalpasStudy.org

Scan here with



NYU Langone Health

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Having a mastectomy?
Concerned about long-term pain?

Join us as we learn how to best prevent chronic pain after a mastectomy



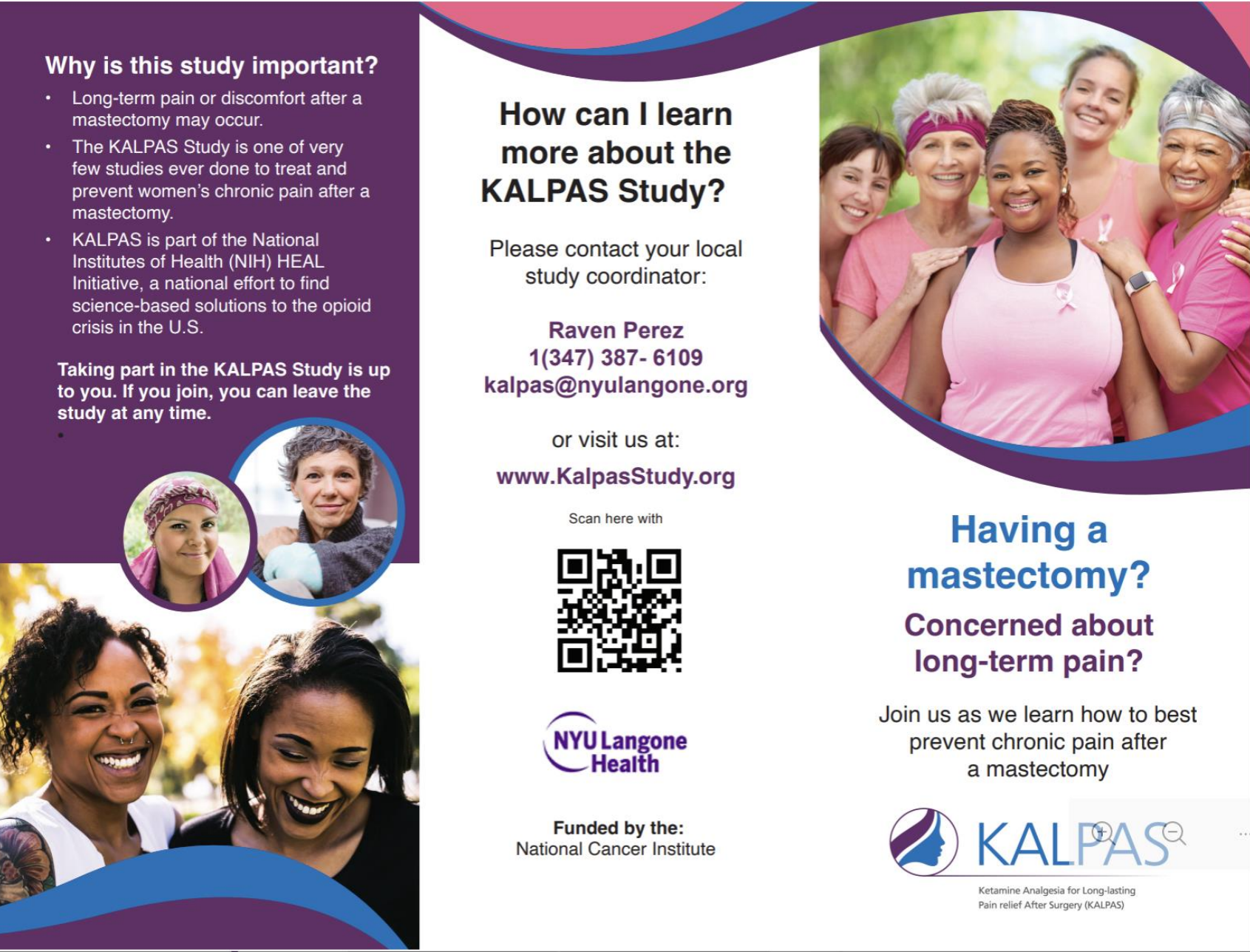


Figure 2: Study brochure



Ketamine Analgesia for Long-lasting Pain relief After Surgery (KALPAS)



Welcome to KALPAS

KALPAS is a nationwide study of how to better manage chronic pain after mastectomy. We will study the effectiveness of a drug called ketamine to prevent post-mastectomy pain syndrome.

Exploring ways to better manage pain after mastectomy

Figure 3: Study website

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