A prospective, multicenter comparative pilot study to evaluate targeting axillary lymph node surgery for patients with clinically node-positive breast cancer (LUCAS study, KBCSG36)

Joon Suk Moon[1,3] , Byeongju Kang[1,3], Jeeyeon Lee[1,3], Ho Yong Park[1,3], In Hee Lee[2,3], Soo Jung Lee[2,3], Yee Soo Chae[2,3]

[1]Department of Surgery, School of Medicine, Kyungpook National University, Daegu, Republic of Korea.[2]Department of Hematology/Oncology, School of Medicine, Kyungpook National University, Daegu, Republic of Korea.
[3]Kyungpook National University Chilgok Hospital, Daegu, Republic of Korea.

Background

- Accurate targeting of metastatic axillary lymph nodes (ALNs) is crucial for staging and surgery in node-positive breast cancer.
- Conventional methods like charcoal tattooing and wire localization have drawbacks such as poor visibility and risk of displacement.
- LuminoMark™, an indocyanine-green (ICG) polymer complex, offers stable lymph node localization, near-infrared visibility without staining, no serious adverse effects, and showed a 100% detection rate in a small previous study.
- LUCAS (Using **LU**minomark vs **C**oventional practice for targeted **A**xillary **S**urgery) study is the first multicenter prospective comparative pilot study evaluating LuminoMark against all conventional ALN targeting methods.

Objectives

- Primary endpoint: To compare the detection success rate of targeted ALN dissection
  - Experimental arm: LuminoMark™
  - Control arm: charcoal tattooing, needle, marking
- Secondary endpoint: To assess the effectiveness and safety of Luminomark™ -based axillary targeting
  - Time from skin incision to detection of target ALNs
  - Total axillary surgery time
  - Concordance between targeted ALNs and sentinel lymph nodes
  - Complication profile, including drug-related adverse reactions, and monitored postoperative recovery through vital signs and 48-hour adverse event surveillance.

Study Design – Methods and Materials

- Prospective, randomized, open-label, multicenter pilot study
- N = 330 patients across 14 institutions in South Korea. 1:1 randomization (LuminoMark™ vs conventional)

- Key Eligibility Criteria
  - Women aged 20–70
  - Primary invasive breast cancer
  - Pathologically proven ALN metastasis
  - Clinical stage T1–T4, N1–3
  - Signed informed consent

- Exclusion Criteria
  - Inflammatory breast cancer
  - Stage IV disease
  - Known hypersensitivity to test materials
  - ALND planned without need for targeting
  - Pregnancy or lactation
  - Active connective-tissue disease involving skin

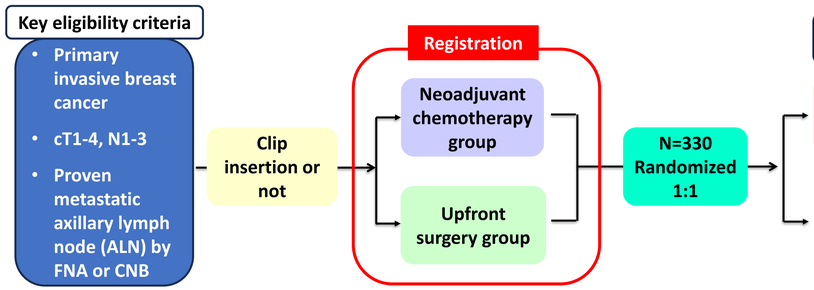


Figure1. Overall Study Flow of the LUCAS Study: Eligibility Confirmation, Clinical Pathway Assignment, and Stratified Randomization to Targeting Methods

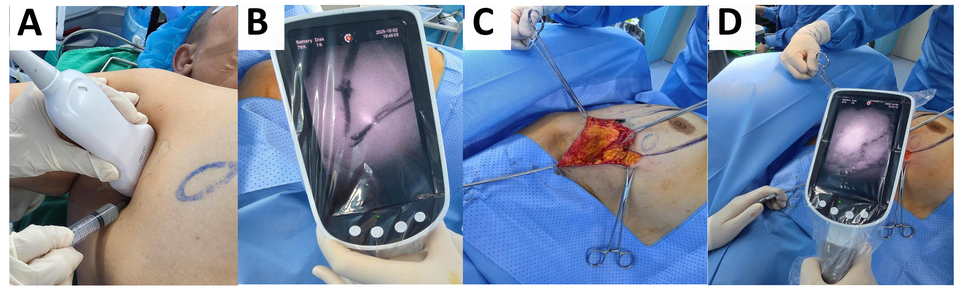


Figure2. Intraoperative Workflow of Targeted Axillary Surgery Using Luminomark™
(A,B) LuminoMark™ injection
(C,D) Dissection following real-time fluorescence signal guidance, and Identification of the targeted axillary lymph node

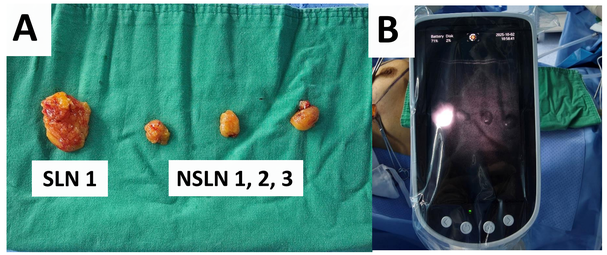


Figure3. Identification of the Targeted Axillary Node and Confirmation of Sentinel Lymph Node Status Using Real-Time Fluorescence Detection
(A) Excised lymph nodes obtained after targeted axillary surgery, separated into sentinel lymph node and non-sentinel lymph nodes using gamma probe
(B) Verification of the targeted node using a real-time fluorescence detector, demonstrating that the fluorescence-positive targeted node corresponds to the sentinel lymph node

Current Status

- Trial activation completed across 14 sites
- Patient registration ongoing
- Expected completion of enrollment by December 2026
- No safety concerns identified to date

Conclusions

- This multicenter pilot study will provide the first comparative evidence on the accuracy, workflow efficiency, and safety of a fluorescence-based localization method (LuminoMark™) versus conventional targeting approaches.
- LUCAS study is expected to inform optimal targeted axillary surgery strategies and guide a future pivotal trial.

Contact

Joon Suk Moon
Kyungpook National University Chilgok Hospital
Email: joonsukm@gmail.com
Phone: +82-10-6609-8216

References

1. J Lee, et al. 5-year oncological outcomes of targeted axillary sampling in pT1-2N1 breast cancer. Asian J Surg. 2019 Jun;42(6):681-687.
2. WH Kim, et al. Ultrasound-Guided Restaging and Localization of Axillary Lymph Nodes After Neoadjuvant Chemotherapy for Guidance of Axillary Surgery in Breast Cancer Patients: Experience with Activated Charcoal. Ann Surg Oncol. 2018 Feb;25(2):494-500.
3. CA Bargon, et al. Sentinel Lymph Node Mapping in Breast Cancer Patients Through Fluorescent Imaging Using Indocyanine Green: The INFLUENCE Trial. Ann Surg. 2022 Nov 1;276(5):913-920.
4. I Kim, et al. The efficacy and safety of indocyanine green-hyaluronic acid mixture (LuminoMark™) for localization in patients with non-palpable breast lesions: a multi-center open-label parallel phase-2 clinical trial. BMC Surg. 2021 Mar 16;21(1):134.
5. YJ Bang, et al. The efficacy and safety of an indocyanine green-hyaluronic acid mixture (LuminoMark™) for localization in patients with non-palpable breast lesions: A multicenter, randomized, open-label, parallel phase 3 clinical trial. Front Oncol. 2023;13:1039670.
6. J Lee, et al. Feasibility of an indocyanine green-hyaluronic acid mixture (LuminoMark™) for targeting suspicious axillary lymph nodes in patients with breast cancer. BMC Cancer. 2024 Dec 30;24(1):1588.
7. Ultrasound-guided dual-localization for axillary nodes before and after neoadjuvant chemotherapy with clip and activated charcoal in breast cancer patients: a feasibility study. Kim et al. BMC Cancer (2019) 19:859.
8. Targeted Axillary Biopsy with Preoperative Ultrasound-Guided Tattooing for Suspicious Axillary Lymph Nodes in Patients with Early Breast Cancer. J Surg Ultrasound Vol. 7, No. 2, 2020.
9. Comparative Study Between Radioisotope Uptake and Fluorescence Intensity of Indocyanine Green for Sentinel Lymph Node Biopsy in Breast Cancer. J Breast Cancer. 2022 Jun;25(3):244-252.
10. Comparison of the indocyanine green dye method versus the combined method of indigo carmine blue dye with indocyanine green fluorescence imaging for sentinel lymph node biopsy in breast conservative therapy for stage ≤IIA breast cancer. Takemoto et al. BMC Women's Health (2018) 18:151.

This presentation is the intellectual property of the author/presenter. Contact them at <<your email address>> for permission to reprint and/or distribute.

© Poster Template by Genigraphics® 1.800.790.4001 www.genigraphics.com

A prospective, multicenter comparative pilot study to evaluate targeting axillary lymph node surgery for patients with clinically node-positive breast cancer (LUCAS study, KBCSG36)

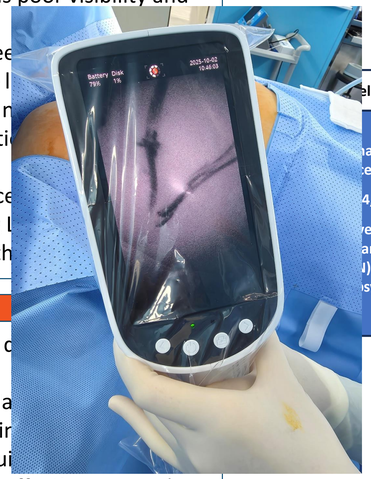
Joon Suk Moon[1,3] , Byeongju Kang[1,3], Jeeyeon Lee[1,3], Ho Yong Park[1,3], In Hee Lee[2,3], Soo Jung Lee[2,3], Yee Soo Chae[2,3]

[1]Department of Surgery, School of Medicine, Kyungpook National University, Daegu, Republic of Korea.[2]Department of Hematology/Oncology, School of Medicine, Kyungpook National University, Daegu, Republic of Korea.
[3]Kyungpook National University Chilgok Hospital, Daegu, Republic of Korea.

Background

- Accurate targeting of metastatic axillary lymph nodes (ALNs) is crucial for staging and surgery in node-positive breast cancer.
- Conventional methods like charcoal tattooing and wire localization have drawbacks such as poor visibility and risk
- Lum
- LUC



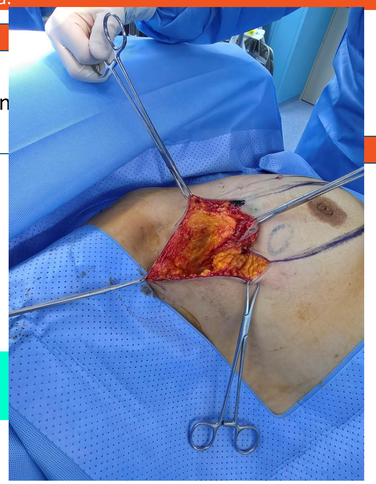


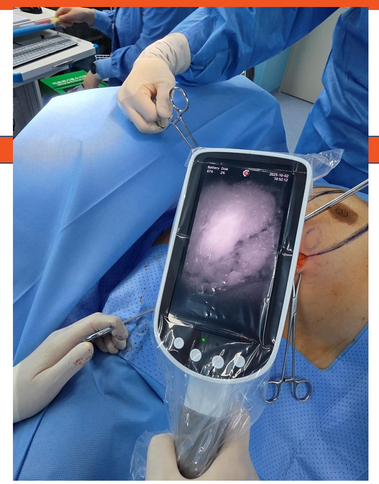
- Prim
  - Ma
  - ir
  - ui
- Secondary endpoint: To assess the effectiveness and safety of Lumin
  - Time fro
  - Total axill
  - Concorda lymph no
  - Complica adverse r recovery event sur

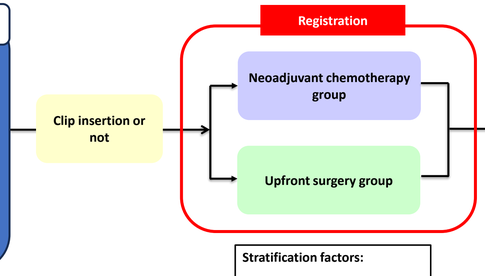


Methods and Materials

- Prospective, randomized, open-label, multicenter pilot study
- N = 330 patients across 14 institutions in Korea. 1:1 randomization (LuminoMark vs conven





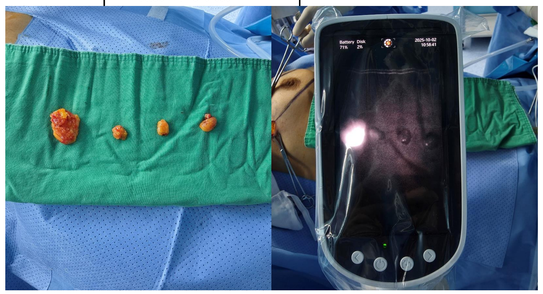


Stratification factors:

- Clip insertion in ALN (Yes vs No)
- Conventional methods
  - Skin marking
  - Wire localization
  - Tattoo with Charcoal

Primary endpoint:

- Success rate of targeting
- Comparison between LuminoMark vs Conventional method



Discussion

Conclusions

Contact

Joon Suk Moon
Kyungpook National University Chilgok Hospital
Email: joonsukm@gmail.com
Phone: +82-10-6609-8216

References

This presentation is the intellectual property of the author/presenter. Contact them at <<your email address>> for permission to reprint and/or distribute.

© Poster Template by Genigraphics® 1.800.790.4001 www.genigraphics.com