

# Comparing pain relief methods after breast surgery: a study on new and traditional approaches

<b>Submission date</b> 12/10/2024	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 15/10/2024	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 15/10/2024	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

There is currently inconclusive evidence on whether liposomal bupivacaine plus bupivacaine hydrochloride (LB-BH) confers better post-lumpectomy analgesia than standard bupivacaine hydrochloride (BH). This study aimed to compare patient-reported pain control and clinical outcomes.

### Who can participate?

Any patients who are able to consent over age 18 who undergoing only lumpectomies of their breast for any reasons.

### What does the study involve?

Receiving LB-BH injection prior to the incision or BH alone and watch for pain management on that side

### What are the possible benefits and risks of participating?

Same benefit of analgesia but 20-30 times less money and no narcotics sent home with, so helping with opioid epidemics

### Where is the study run from?

University of Michigan Health-Sparrow (USA)

### When is the study starting and how long is it expected to run for?

February 2023 to February 2024

### Who is funding the study?

Investigator initiated and funded

### Who is the main contact?

Irada Mamukadze, [irada.mamukadze@umhsparrow.org](mailto:irada.mamukadze@umhsparrow.org)

## Contact information

### Type(s)

Scientific, Principal investigator

### Contact name

Dr Thais Fortes

### Contact details

1215 E. Michigan ave  
Lansing  
United States of America  
48912  
+1 9372191095  
thais.fortes@umhsparrow.org

### Type(s)

Public, Scientific

### Contact name

Dr Irada Mamukadze

### ORCID ID

<https://orcid.org/0009-0005-0865-0926>

### Contact details

935 Whittier Dr  
East Lansing  
United States of America  
48823  
+1 9372191095  
Irada.Mamukadze@umhsparrow.org

## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

1967230-3

## Study information

### Scientific Title

Comparing post-lumpectomy analgesia using enhanced recovery after surgery (ERAS) protocol with and without liposomal bupivacaine: randomized controlled trial

**Acronym**

ERAS

**Study objectives**

Liposomal Bupivacaine and Bupivacaine hydrochloride have same efficacy on pain control

**Ethics approval required**

Ethics approval required

**Ethics approval(s)**

approved 15/02/2024, Sparrow Health System IRB (1215 Michigan Avenue, Lansing, MI, 48912, United States of America; +1 5173645016; irb@sparrow.org), ref: 2228

**Study design**

Single-center patient-blinded prospective randomized controlled trial who undergo lumpectomy

**Primary study design**

Interventional

**Study type(s)**

Efficacy

**Health condition(s) or problem(s) studied**

Use of bupivacaine hydrochloride during lumpectomy surgery

**Interventions**

Patients were randomized in a 1:1 ratio to either the intervention group Bupivacaine Liposomal with Bupivacaine Hydrochloride (LB-BH) or Bupivacaine Hydrochloride alone (BH) using a clinical trial randomization tool from the National Cancer Institute. Randomization was stratified based on the recruitment site and type of surgery (lumpectomies with and without SLNB). The treatment groups were balanced using randomly assigned numbers. The injection of LB-BH or BH were given prior to incision. Then on day 2 of post surgery a nurse called to ask for pain level 0-10 with 0 being no pain at all and 10 being the worst pain they ever had , then same question was asked on post surgery day 9. Then, they were chart checked from electronic medical record to see if they called offices for pain related questions or asking for opioid pain medications or had ED visits.

**Intervention Type**

Drug

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Bupivacaine hydrochloride and bupivacaine hydrochloride

**Primary outcome(s)**

Pain measured using NRS on day 2 and day 9 post surgery

**Key secondary outcome(s))**

Adjunctive opioid use, pain-related ED visits, office calls, requests for pain scripts measured using patient records after day 9 post surgery

**Completion date**

28/02/2024

## Eligibility

**Key inclusion criteria**

Adults over the age of 18 who undergo lumpectomies and able to consent

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Upper age limit**

99 years

**Sex**

All

**Total final enrolment**

76

**Key exclusion criteria**

1. Patients undergoing any other procedures other than lumpectomies
2. Patients who are getting lumpectomies with any other procedures

**Date of first enrolment**

21/04/2023

**Date of final enrolment**

23/02/2024

## Locations

**Countries of recruitment**

United States of America

**Study participating centre**

**University of Michigan health-Sparrow**  
1200 E Michigan ave  
Lansing  
United States of America  
48912

## Sponsor information

### Organisation

University Of Michigan-Sparrow Health

## Funder(s)

### Funder type

Not defined

### Funder Name

Not Consumed

### Alternative Name(s)

### Funding Body Type

Private sector organisation

### Funding Body Subtype

Other non-profit organizations

### Location

United States of America

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request  
irada.mamukadze@umhsparrow.org

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
-------------	---------	--------------	------------	----------------	-----------------

