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

Submission date
12/10/2024

Recruitment status
No longer recruiting

Registration date
15/10/2024

Overall study status
Completed

Last Edited
15/10/2024

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] 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?
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Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Efficacy

Participant information sheet
No participant information sheet available

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

Pharmaceutical study type(s)
Bioequivalence

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Bupivacaine hydrochloride and bupivacaine hydrochloride

Primary outcome measure
Pain measured using NRS on day 2 and day 9 post surgery

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

Overall study start date
15/02/2023

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
99 Years

Sex
Both

Target number of participants
200

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
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48912

Sponsor information

Organisation
University Of Michigan-Sparrow Health

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Sponsor type
Research organisation

Website
https://www.uofmhealthsparrow.org/

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

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
15/10/2024

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
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IPD sharing plan summary
Available on request