ISRCTN99910605 https://doi.org/10.1186/ISRCTN99910605

A study of lidocaine jelly for pain relief in women receiving gonadotropin-releasing hormone analog injection during breast cancer treatment

Submission date
05/12/2022

Recruitment status
No longer recruiting

Registration date
09/12/2022

Overall study status
Completed

Last Edited
03/02/2023

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The purpose of this study was to evaluate the pain and anxiety scores of women receiving gonadotropin-releasing hormone analog (GnRHa) injections during breast cancer treatment and to determine whether an application of a topical anesthetic agent before the GnRHa injection is effective in reducing pain and anxiety.

Who can participate?
Premenopausal women with hormone receptor-positive breast cancer after surgery who received GnRHa injection

What does the study involve?
Participants will have topical lidocaine jelly applied before GnRHa injection.

What are the possible benefits and risks of participating?
The possible benefits of participating include the improvement of pain and anxiety and there are no anticipated risks.

Where is the study run from?
Changhua Christian Hospital (Taiwan)

When is the study starting and how long is it expected to run for?
February 2019 to July 2023

Who is funding the study?
Changhua Christian Hospital (Taiwan)

Who is the main contact?
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Contact information

Type(s)
Principal investigator

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Additional identifiers

Study information

Scientific Title
Comparison of pain and anxiety in premenopausal women with hormone receptor-positive breast cancer receiving gonadotropin-releasing hormone analog injection before and after application of topical lidocaine jelly

Study objectives
Application of topical lidocaine jelly before the injection of gonadotropin-releasing hormone analog (GnRHa) would reduce pain or anxiety in premenopausal women with hormone receptor-positive breast cancer

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/07/2019, Institutional Review Board of Changhua Christian Hospital (No. 176, Zhonghua Rd, Changhua City, Changhua County, 500, Taiwan; +886 47238595; d9065@cch.org.tw), ref: CCH IRB No.:190708

Primary study design
Interventional

Study design
Prospective non-randomized open-label trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Premenopausal women with hormone receptor-positive breast cancer

Interventions
Questionnaires were used in the evaluation of pain and anxiety experienced during four cycles (1-4th) of GnRHa (goserelin or leuprorelin) injections and recorded as the baseline. Pain and anxiety scores were graded using the visual analog scale (VAS), ranging from 0 (no or minimal pain or anxiety) to 10 (maximal pain or anxiety experienced). During the next four cycles (5-8th) of GnRHa injections, patients were provided with lidocaine jelly and instructed to use a single application (5 g) of topical gel 5-10 mins before the injection of GnRHa. And the pain and anxiety scores were recorded after GnRHa injection.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Lidocaine jelly

Primary outcome(s)
Pain and anxiety measured using a visual analog scale (VAS) at baseline and the 1st to 8th cycles of GnRHa injections

Key secondary outcome(s)
Levels of follicle-stimulating hormone (FSH), luteinizing hormone (LH), and estradiol measured using a blood test before and after the GnRHa injection

Completion date
21/07/2023

Eligibility

Key inclusion criteria
Premenopausal women with hormone receptor-positive breast cancer who had undergone breast cancer operations and were indicated for GnRHa injection

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Unwilling to receive application of topical lidocaine jelly
2. Refuse questionnaire survey of pain and anxiety score

Date of first enrolment
01/08/2019

Date of final enrolment
30/01/2023

Locations

Countries of recruitment
Taiwan

Study participating centre
Changhua Christian Hospital
No. 176, Zhonghua Rd
Changhua County
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500

Sponsor information

Organisation
Changhua Christian Hospital

ROR

https://ror.org/05d9dtr71

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Changhua Christian Hospital

Alternative Name(s)
CCH

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Taiwan

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date