

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 09/12/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 03/02/2023	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

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

Study design

Prospective non-randomized open-label trial

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

No participant information sheet available

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 measure

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

Secondary outcome measures

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

Overall study start date

01/02/2019

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

Age group

Adult

Sex

Female

Target number of participants

60

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

Taiwan

500

Sponsor information

Organisation

Changhua Christian Hospital

Sponsor details

135 Nanxiao Street

Changhua County

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500

+886 4 7238595

D3925c@cch.org.tw

Sponsor type

Hospital/treatment centre

Website

https://www2.cch.org.tw/cch_english/About_CCH.aspx?Page=1

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

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

30/12/2023

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