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Ultrasound-guided steroid injection and rehabilitation exercises to ease shoulder pain in women who have undergone surgery for breast cancer

Submission date
16/08/2022

Recruitment status
Recruiting

Registration date
04/10/2022

Overall study status
Completed

Last Edited
04/10/2022

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Recent advances in cancer treatments significantly improved the overall survival of breast cancer (BC) patients. However, BC survivors might often be affected by several disabling cancer treatment adverse effects with crucial implications for physical function and quality of life.
In this scenario, shoulder pain called subacromial pain syndrome (SPS) is very common in BC survivors, causing significant pain and upper limb dysfunction. Several treatments have been proposed to improve pain in patients with SPS; however, there are still some controversies about the optimal therapeutic approach for BC survivors. Therefore, in this study we aim to assess the efficacy of ultrasound (US)-guided injections below the uppermost part of the shoulder blade, the subacromial bursa, followed by a personalized rehabilitation program for breast cancer (BC) survivors.

Who can participate?
Adult women with subacromial pain syndrome without tendon lesions and with a history of post-surgical non-metastatic BC

What does the study involve?
Our findings might provide evidence supporting the role of a multidisciplinary approach including US-guided corticosteroid injections combined with a personalized rehabilitation program in improving pain intensity and quality of life of BC survivors with sub-acromial pain syndrome. Some patients will join Group A and undergo interdisciplinary treatment including US-guided injections in the subacromial bursa including triamcinolone acetonide, a steroid, combined with lidocaine, a pain medication, followed by a supervised rehabilitation program. Other patients will join Group B and undergo only the US-guided injections in the subacromial bursa without any rehabilitative treatment.

What are the possible benefits and risks of participating?
The procedures assessed in this study are already used in common clinical practice, so no additional benefits and risks associated with participation have been identified.

Where is the study run from?
National Hospital S.S. Antonio and Biagio and Cesare Arrigo (Italy)

When is the study starting and how long is it expected to run for?
April 2021 to April 2023

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Lorenzo Lippi
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Contact information

Type(s)
Principal investigator

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Additional identifiers

Protocol serial number
0005266

Study information

Scientific Title
Efficacy of ultrasound-guided corticosteroid injection combined with personalized rehabilitation in breast cancer women with subacromial pain syndrome: A pilot randomized clinical study

Study objectives
Rehabilitation exercise combined with ultrasound-guided corticosteroids injection might provide additional benefits in pain relief and upper limb function for breast cancer patients with subacromial pain syndrome

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/03/2022, Local Ethics Committee (Comitato Etico Interaziendale A.O. “SS. Antonio e Biagio e Cesare Arrigo” di Alessandria, Via Santa Caterina da Siena n° 30, 15121 Alessandria, Italy; +39 0131/206974-6627-6764; ecomitato@ospedale.al.it), ref: ASO.RRF.22.01

Primary study design
Interventional

Study design
Pilot randomized controlled study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Subacromial pain syndrome without tendon lesions following surgery for breast cancer

Interventions
Enrolled participants will be randomly assigned by a computer-generated randomization process with a 1:1 allocation without blocks. Participants randomized to Group A will undergo an interdisciplinary treatment including ultrasound (US)-guided percutaneous injections in the subacromial bursa (1 ml of 40 mg triamcinolone acetonide combined with 3 ml of 1% lidocaine), followed by a supervised rehabilitation program, including passive and active mobilization exercises, stretching exercises and myofascial release techniques followed by active extra- and intra-rotation exercises with elastic bands, exercises for the scapular stabilizing muscles and proprioceptive exercises. On the contrary, Group B will undergo only US-guided percutaneous injections in the subacromial bursa without any rehabilitative treatment.

Intervention Type
Mixed

Primary outcome(s)
Pain measured using the Numerical Pain Rating Scale at baseline (T0), after 1 week (T1), and after three months of follow-up (T2)

Key secondary outcome(s)
1. Isometric muscle strength measured using the Hand Grip Strength test (HGS) (Jamar hydraulic hand dynamometer Sammons Preston, Rolyon, Bolingbrook, IL, USA) at baseline (T0), after 1 week (T1), and after three months of follow-up (T2)
2. Shoulder function measured using the Oxford Shoulder Score (OSS) at baseline (T0), after 1 week (T1), and after three months of follow-up (T2)
3. Quality of Life measured using the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ - C30) at baseline (T0), after 1 week (T1), and after three months of follow-up (T2)
4. Patient satisfaction measured using the Global Perceived Effect (GPE) scale, after 1 week (T1), and after three months of follow-up (T2)
5. Safety measured using registering minor and major adverse events during the study period

Completion date
01/04/2023

Eligibility

Key inclusion criteria
1. Aged 18 years old and over
2. Female gender
3. Surgery for breast cancer
4. Subacromial pain syndrome
5. Numerical Pain Rating Scale (NPRS) > 5
6. Signed informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Female

Key exclusion criteria
1. Allergies to triamcinolone or lidocaine
2. Severe thrombocytopenia (<10,000plt) or bleeding disorders
3. Chemotherapy or radiotherapy in progress
4. Metastatic disease

5. Shoulder tendon lesions
6. Cognitive impairment or psychiatric disorders
7. Pregnancy or breastfeeding

Date of first enrolment
10/03/2022

Date of final enrolment
01/04/2323

Locations

Countries of recruitment
Italy

Study participating centre
National Hospital S.S. Antonio and Biagio and Cesare Arrigo
Via Venezia, 16
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Sponsor information

Organisation
Azienda Ospedaliera Nazionale SS. Antonio e Biagio e Cesare Arrigo

ROR
https://ror.org/04yxyzj48

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Lorenzo Lippi, lorenzolippi.mt@gmail.com. Data are stored as an XLS database and will be available after the end of the study after appropriate request, for any type of analysis. All personal data will be processed in accordance with the General Regulation on the protection of personal data EU 2016/679 and Italian Legislative Decree 196/2003. Privacy will be guaranteed for any study participants.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1	08/02/2022	19/08/2022	No	Yes
Protocol file	version 1	08/02/2022	19/08/2022	No	No