ISRCTN10358568 https://doi.org/10.1186/ISRCTN10358568

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
lorenzolippi.mt@gmail.com

Contact information

Type(s)
Principal Investigator

Contact name
Dr Lorenzo Lippi

Contact details
Via Venezia, 16
Alessandria
Italy
15121
+39 3485908877
lorenzolippi.mt@gmail.com

Type(s)
Principal Investigator

Contact name
Dr Lorenzo Lippi

ORCID ID
http://orcid.org/0000-0001-9035-1485

Contact details
Via Venezia, 16
Alessandria
Italy
15121
+39 3485908877
lorenzo.lippi@esterni.ospedale.al.it

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Study design
Pilot randomized controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See trial outputs table

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

Secondary outcome measures
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

Overall study start date
01/04/2021

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

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
20 patients (10 for each treatment arm)

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
Alessandria
Italy
15121

Sponsor information

Organisation

Azienda Ospedaliera Nazionale SS. Antonio e Biagio e Cesare Arrigo

Sponsor details
Via Venezia, 16
Alessandria
Italy
15121
+39 (0)131 206111
info@ospedale.al.it

Sponsor type
Hospital/treatment centre

Website
http://www.ospedale.al.it/

ROR
https://ror.org/04yxyzj48

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
The responsible for the dissemination strategy and the communication will be the supervisor of this cornerstone topic and will provide solutions for eventual issues and delay in information diffusion and circulation, defining a precise schedule for the dissemination of the study results. The dissemination will be guided by the sharing, transparency, and transferability of the results obtained and will contribute to the final goal of this project which is the transferability of the proposed intervention: this approach is the most suitable for achieving the project's objectives. The key strategy of this proposal will be the widest possible spread of our results. This will be obtained through the largest involvement of the public with particular emphasis on diversification of interlocutors and transparency in order to help in improving knowledge in physicians, healthcare operators, patients, and caregivers. A strong involvement of the breast cancer associations, cancer patients, institutions, media and stakeholders will be performed to create and sustain a close communication of the new insights progressively provided by this project. The final step of this process will culminate in the involvement of the institutions in the communication of the results through local, national and European media and their involvement in the discussion of implementation of the results in the routine cancer patients care.

Intention to publish date
30/04/2024

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