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Electrochemotherapy for breast cancer patients with skin metastases

Submission date
27/03/2017

Recruitment status
No longer recruiting

Registration date
29/03/2017

Overall study status
Completed

Last Edited
10/09/2019

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
Electrochemotherapy (ECT) is a safe skin-directed treatment for cancer which combines drug treatment with short electric pulses to the tumor. The procedure lasts 20-40 minutes and is generally performed under sedation. It generally allows for a fast recovery with low discomfort. The aims of this study are to find out how well ECT works in patients with breast cancer that has spread to the skin (cutaneous metastases), and to find out which patients have the best response to the treatment.

Who can participate?
Women (men can be also included) with skin metastases from breast cancer who are not suitable candidates for surgery, radiotherapy or systemic treatments

What does the study involve?
All participants receive ECT treatment according to routine clinical practice under general sedation or local anaesthetic, according to the amount of tumor. The patients have to stay in hospital 4-6 hours after the procedure or until the following day, according to their general conditions and specific requirements. After discharge, the patients attend outpatient clinics for regular clinical examination of treated tumors. They are asked to answer to some brief questionnaires regarding their quality of life and symptoms related to skin metastases.

What are the possible benefits and risks of participating?
Taking part in this study can have many benefits for breast cancer patients with skin metastases. Participants have the support of an experienced team of health care providers, who closely monitor the tumor response to ECT, its possible side effects as well as the disease course. Collecting information about other cancer treatments given before or after ECT could help with finding new effective treatment strategies. Finally, the information gathered will help to gain insights into patient quality of life and to improve the overall treatment of other patients with skin metastases. There are no specific risks related to this study, as the treatment is part of routine clinical practice. As such, it is expected that patients may have local side effects (skin toxicity) and, very rarely, systemic side effects (fever, lung toxicity) from the ECT treatment.

Where is the study run from?
This study is being run by the Italian Senologic Group for Electrochemotherapy (GISEL) and takes place in several hospitals across Italy.

When is the study starting and how long is it expected to run for?
April 2016 to October 2021

Who is funding the study?
Associazione Piccoli Punti Onlus (Italy)

Who is the main contact?
Dr Luca G. Campana
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
GISEL (Gruppo Italiano Senologico per l'ELettrochemioterapia) protocol: prospective multicenter registry of breast cancer patients with skin metastases treated by electrochemotherapy

Acronym
GISEL (Italian Senologic Group for Electrochemotherapy)

Study objectives

The primary objective of the study is to confirm the results obtained in the previous multicenter retrospective study from the GISEL group. In that study, the breast cancer patients with "luminal A-like" disease who underwent electrochemotherapy with bleomycin achieved a significantly higher complete response rate compared with other surrogate subtypes, defined according to the St. Gallen classification. (73.9% vs 54.7%, P = 0.02). In the present study the trialists intend to verify, on a large perspective series, if the rate of complete response in patients with “luminal A-like" breast cancer is significantly higher than in other subgroups.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Veneto Institute of Oncology, Padova, Italy; Ethics Committee for Clinical Trial (Istituto Oncologico Veneto IOV-IRCCS, Padova; Comitato Etico per la Sperimentazione Clinica (CESC)), 20 /02/2017, ref: CE IOV: 2017/11

Study design
Prospective multicenter observational study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Cutaneous metastases from breast cancer

Interventions
Patients will be enrolled based on the inclusion criteria currently employed in the clinical practice. The percentage of women with "luminal A-like" breast cancer in the previous, retrospective study was 18.4%. The trialists hypothesize to have the same patient distribution in the present study. In order to test the hypothesis of a significant difference between “luminal A-like” tumors and the other surrogate subtypes with a statistical power of 90% and a significance level of 5%, some 351 patients are required (64 in the "A luminal-like" group and 287 in the group non-"luminal A-like"). Taking into account also a 15% patient dropout, it is necessary to recruit a study population of 404 patients.

All patients will receive treatment with electrochemotherapy according to the European Standard Operating Procedures of Electrochemotherapy (ESOPE). Participating in this study involves receiving treatment with ECT under general sedation or local anaesthesia, according to the amount of skin tumor involvement; the patients will have to stay in hospital 4-6 hours after the procedure or until the following day, according to their general conditions and specific requirements. After discharge, the patients will attend the outpatient clinics for regular clinical examination of treated tumors. They will be asked to answer to some brief questionnaires regarding their quality of life and symptoms related to skin metastases. The planned follow-up time planned for each patient is 12 months leading to a total study duration of four years. After the fourth year, the database could be maintained open to further accrual in the event of insufficient patient accrual or if, based on collected data, additional research questions arise.

Intervention Type
Mixed

Primary outcome(s)
1. Local response to the treatment, assessed using clinical examination and graded according to the Response Evaluation Criteria In Solid Tumors (RECIST) at 4 and 8 weeks
2. Treatment toxicity, assessed using clinical examination and graded according to the Common Terminology Criteria for Adverse Events (CTCAE v4.0) at 1 and 2 weeks and 1, 2, 3, 6 and 12 months

Key secondary outcome(s))
1. Local progression-free survival (LPFS), assessed using physical examination at 1, 2 , 3 , 6 and 12 months (and every 6 months thereafter)
2. Quality of life, measured using the EQ-5D questionnaire at 1 and 2 weeks, and at 1, 2, 3, 6 and 12 months

Completion date
21/10/2021

Eligibility

Key inclusion criteria
1. Cutaneous metastases from breast cancer
2. No indication to surgical resection
3. No indication to treatment with radiotherapy
4. Ineligibility or unresponsiveness to systemic cancer treatment
5. Maximum tumor depth (from the skin layer): 3 cm
6. Patient's life expectancy greater than 4 months
7. Normal hematology, hepatic and renal function
8. Performance status (ECOG) ≤2
9. At least 18 years old

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. History of allergic reaction to bleomycin
2. Exceeding the maximum cumulative dose of bleomycin (250,000 IU / m2)

3. Severe impairment of lung, liver or kidney function
4. History of epilepsy
5. Presence of a cardiac pacemaker
6. Serious cardiac arrhythmias
7. Pregnancy or lactation
8. Unwillingness to attend the clinic for follow-up visits
9. Impaired respiratory function or presence of pulmonary fibrosis

Date of first enrolment
06/03/2017

Date of final enrolment
06/03/2021

Locations

Countries of recruitment
Italy

Study participating centre
Veneto Institute of Oncology IOV-IRCCS
Padova
Italy
35128

Study participating centre
University of Naples
Naples
Italy
80138

Study participating centre
Ospedale Sant'Orsola-Malpighi
Bologna
Italy
40138

Study participating centre
Fondazione IRCCS - Istituto Nazionale dei Tumori
Milano
Italy
20133

Study participating centre
IRCCS San Martino-IST
Genova
Italy
16132

Study participating centre
Fondazione Tommaso Campanella
Catanzaro
Italy
88100

Study participating centre
Istituto Tumori "Giovanni Paolo II"
Bari
Italy
70124

Study participating centre
IRCCS CROB
Rionero in Vulture
Italy
85028

Study participating centre
Istituto Dermatologico San Gallicano
Roma
Italy
00144

Study participating centre
Istituto Tumori Napoli - Fondazione G. Pascale
Naples
Italy
80131

Study participating centre

Ospedale Oncologico Armando Businco
Cagliari
Italy
09121

Study participating centre
A.O.U. Citta della Salute e della Scienza di Torino
Torino
Italy
10126

Study participating centre
Policlinico Umberto I - Università La Sapienza
Rome
Italy
00161

Study participating centre
Humanitas Centro Catanese di Oncologia
Catania
Italy
95126

Sponsor information

Organisation
Veneto Institute of Oncology IOv-IRCCS

Organisation
University of Padova

Organisation
Istituto Oncologico Veneto

ROR
https://ror.org/01xcjmy57

Funder(s)

Funder type
Charity

Funder Name
Associazione Piccoli Punti Onlus (Italy)

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 Dr Luca G. Campana (luca.campana@unipd.it).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes