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Electrochemotherapy in basal cell carcinoma

Submission date	Recruitment status	[_] Prospectively registered
13/03/2017	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
24/03/2017	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
26/11/2020	Cancer	

Plain English summary of protocol

Background and study aims
Basal cell carcinoma (BCC) is one of the most common types of skin cancer. It is usually caused by sun exposure and causes lumps, moles, lesions or patches of discoloured skin. It has a low risk of spreading, and when it is found early it can usually be treated through simple procedures, such as removal of the affected skin. As BCC is a slow-growing cancer it is important to consider that the cancer could return. During the last decade, electrochemotherapy (ECT) has become a well-established treatment for skin cancers. ECT is a way of getting chemotherapy (cancer medication) into the cancer cells by injecting chemotherapy into the blood and using an electrical pulse directly on the cancerous area (skin lesions). However, there is not a lot of evidence showing that it can help prevent BCC from returning. The aim of this study is to examine the feasibility, efficacy and toxicity of ECT in BCC to gain insights of long-term patient outcomes.

Who can participate?
Adults aged 18 and older with basal cell carcinoma.

What does the study involve?
Participants are enrolled in the study prior to their ECT treatment. After the treatment, participants are monitored for toxicity from the treatment until they are discharged from the hospital. They are then followed up at one week and one, two, six and 12 months after the treatment to assess the size of their skin lesions and toxicity of the treatment. In order to rule out long-term toxicity and tumour recurrence participants are then monitored every six to 12 months.

What are the possible benefits and risks of participating?
There are no notable benefits or risks with participating.

Where is the study run from?
Veneto Institute of Oncology IOV-IRCCS (Italy)

When is the study starting and how long is it expected to run for?
December 2005 to March 2013

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Luca Giovanni Campana

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
03/2006

Study information

Scientific Title
Efficacy and safety of electrochemotherapy in basal cell carcinoma: A single-arm observational cohort study

Study objectives
The aim of this study is to examine the feasibility, efficacy and toxicity of electrochemotherapy (ECT) in basal cell carcinoma (BCC) to gain insights into long-term patient outcomes.

Ethics approval required
Old ethics approval format

Ethics approval(s)

This study was to the local Ethic Committee of the University of Padova. As this study is observational and concerns a standard procedure (electrochemotherapy), which is already part of the routine clinical practice, only a notificiation is required and not a formal approval.

Study design
Single-arm observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Basal cell carcinoma (any type): local, locally-advanced, metastatic

Interventions
Participants are prospectively enrolled from the outpatient clinic. During a day-surgery stay in hospital, they undergo treatment for their basal cell carcinoma (BCC) with electrochemotherapy (ECT) according to the European Standard Operative Procedures for ECT (ESOPE). Accordingly, the type of anaesthesia (local anaesthesia or mild general sedation), the cytotoxic agent (bleomycin or cisplatin) and its route of administration (systemic vs intratumoral) are selected based on patient characteristics, disease extent and tumor anatomical location. Systemic bleomycin (at the dosage of 15,000 IU/m2) is administered intravenously, as a one minute bolus; alternatively, it is injected intratumorally on each tumor at a dosage of 250-1,000 IU/cm3 of tumor volume. Shortly after, electric pulses are applied to the tumor by means of a needle electrode connected to electric pulse generator for clinical electroporation. Participants are monitored for two to four hours or up to the following morning, according to disease burden and to the standard level of care, and then discharged.

Participants are then followed up at one week and at one, two, six and 12 months after the ECT for tumor response assessment. Finally, they are followed on a six or 12-month basis, in order to rule out long-term toxicity and local tumor recurrence. Treated lesions are clinically evaluated by inspection and their size assessed by means of a caliper in accordance with the Response Evaluation Criteria in Solid Tumors (RECIST). Local and systemic toxicity is graded according to the Common Terminology Criteria for Adverse Events (CTCAE).

Intervention Type
Procedure/Surgery

Primary outcome measure

1. Local tumor response is clinically measured using the Response Evaluation Criteria in Solid Tumors (RECIST) criteria at one and two months
2. Treatment toxicity is measured by means of clinical examination and graded by using the Common Terminology Criteria for Adverse Events (CTCAE) criteria at the end of the procedure, during the hospital stay (indicatively at 4:00 pm of the day of treatment and 8:00 am of the following day), week one, one, two, six and 12 months after surgery and every six to 12 months thereafter

Secondary outcome measures
Local tumor control is assessed by inspection of the skin at six and 12 months after ECT and on a six to 12-month basis thereafter.

Overall study start date
09/12/2005

Completion date
10/03/2017

Eligibility

Key inclusion criteria
1. Aged 18 years or older
2. Cutaneous / subcutaneous histologically confirmed skin metastases or primary or recurrent basal cell carcinoma (BCC) or squamous cell carcinoma (SCC)
3. Measurable disease
4. Unresponsive or unsuitable for conventional treatments
5. In case of local BCC, the patients have to present with ≥2 tumors when located in the face or with ≥3 tumors when located in other anatomical regions
6. Patients with laBCC had at least one lesion >2 cm or any size plus 2 risk features so that surgical resection was deemed inappropriate; moreover, laBCC have to be previously irradiated or, alternatively, radiation therapy have to be considered contraindicated or inappropriate (e.g. multifocal disease)
7. All subject have to be discussed in the frame of a multidisciplinary team
8. Tumor size smaller than 3 cm in thickness
9. Tumor not deeper than 3 cm
10. No concomitant treatments one month before and two months following ECT
11. Eastern Cooperative Oncology Group (ECOG) performance status: 0-2
12. Life expectancy of at least three months
13. Normal hematologic, hepatic and renal function

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex

Both

Target number of participants
50-100

Total final enrolment
84

Key exclusion criteria
1. Abnormal respiratory function
2. A cardiac pacemaker or arrhythmias
3. Previous maximal exposure to bleomycin
4. History of seizures

Date of first enrolment
01/04/2006

Date of final enrolment
09/05/2016

Locations

Countries of recruitment
Italy

Study participating centre
Veneto Institute of Oncology IOV-IRCCS
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Sponsor information

Organisation
Veneto Institute of Oncology IOv-IRCCS

Sponsor details
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Sponsor type

Hospital/treatment centre

ROR
https://ror.org/01xcjmy57

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
10/03/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Luca G. Campana at luca.campana@iov.veneto.it

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		24/03/2017	06/04/2017	No	Yes
Results article	results	31/05/2017	26/11/2020	Yes	No