

Efficiency of electrochemotherapy in treatment of head and neck cancer

Submission date 04/01/2016	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 07/01/2016	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 18/10/2022	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol

Background and study aims

Electrochemotherapy is a cancer treatment. It works through injection of a chemotherapeutic drug (such as bleomycin) and then applying an electric pulse to send the chemotherapy into the cancer cells. Between 70-80% of tumours respond to this treatment. It is currently used for treating skin cancer in 150 centres throughout Europe. The aim of this study is to test how effective and safe electrochemotherapy is in patients with head and neck cancers and measure the concentration of drug bleomycin in the serum (blood) and in the tumour itself.

Who can participate?

Adults (aged over 18) with head or neck cancer, that have not had chemotherapy for at least 2 weeks and are expected to live for more than 3 months.

What does the study involve?

All participants have the electrochemotherapy treatment. The procedure is standardized and is performed according to the published Standard Operating Procedure (SOP) for electrochemotherapy. The chemotherapy drug Bleomycin is injected intravenously (through a needle in a vein) in dose of 15,000 IU/m². After 8 minutes, electric pulses are delivered to the tumour in order to send the bleomycin into the cancer cells. The response of the tumour to the treatment is assessed at one month and again at two months.

What are the possible benefits and risks of participating?

So far minimal or no side effects have been reported. Due to the pain caused by the electric pulses, local or general anaesthesia will be needed. There may be some reddening of the skin but no pain after the treatment is complete is expected.

Where is the study run from?

The University Medical Centre Ljubljana and Institute of Oncology Ljubljana (Slovenia)

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

July 2015 to December 2017

Who is funding the study?
Slovenian Research Agency

Who is the main contact?
1. Professor Gregor Sersa (scientific)
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Scientific

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Additional identifiers

Study information

Scientific Title

Efficiency of electrochemotherapy in treatment of head and neck cancer: a multicentre, interventional study

Acronym

NECT

Study objectives

The aim of the study is to evaluate the efficacy and safety of electrochemotherapy with bleomycin and improvement of therapeutic procedures in patients with cancer in head and neck region treated with electrochemotherapy.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Republic of Slovenia National Ethics Committee, 23/06/2015, ref: KME 058/06/15

Primary study design

Interventional

Study design

Multicentre interventional study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Cancer in the head and neck region

Interventions

All patients are treated with electrochemotherapy with bleomycin, according to European Standard Operating Procedures of Electrochemotherapy. Bleomycin will be injected intravenously in a dose of 15,000 IU/m² skin surface. The electric pulses will be delivered by electrodes to the tumors generated by electric pulse generator Cliniporator (IGEA, Carpi, Italy) 8-28 minutes after bleomycin injection. During the procedure tumor tissue and blood samples will be collected for the purpose of pharmacological analysis. Patients will be followed up at 1, 2, 4, 8, 12, 18 and 24 months after the treatment.

Intervention Type

Procedure/Surgery

Primary outcome(s)

1. Antitumor efficiency of electrochemotherapy, evaluated by measurement of tumor response in accordance with RECIST criteria, 1 and 2 months after the treatment
2. Safety of electrochemotherapy. Any adverse events will be recorded according to National Cancer Institute (NCI) criteria

Key secondary outcome(s)

Setting a time frame of optimal concentration of bleomycin in tumors and plasma for effective electrochemotherapy treatment.

Completion date

31/12/2017

Eligibility

Key inclusion criteria

1. Histologically or cytologically confirmed carcinoma and/or recurrent disease and/or multiple nodules on different sites and/or tumors that require reconstruction with the local and / or remote lobes and/or tumors located at the sites where after excision poor aesthetic outcome is expected and/or patients who refuse other treatment options
2. Age over 18
3. The life expectancy more than 3 months
4. Performance status Karnofsky ≥ 70 or (World Health Organization) WHO ≤ 2
5. Chemotherapy free interval at least 2 weeks
6. Patient must be mentally capable of understanding the information given
7. Patient must give informed consent
8. Patient must be discussed at the multidisciplinary team

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Total final enrolment

78

Key exclusion criteria

1. Lesions which are not suitable for treatment with electrochemotherapy (invasion into the bone, infiltration of large vessels)
2. Life-threatening infection and/or heart failure and/or liver failure and/or other severe systemic pathologies
3. Significant reduction in respiratory function
4. Age less than 18 years
5. Coagulation disturbances
6. Cumulative dose of 250 mg/m² bleomycin received
7. Allergic reaction to bleomycin
8. Impaired kidney function (creatinin $> 150 \mu\text{mol/l}$)
9. Patients with epilepsy

10. Pregnancy

11. Patients incapable to understand the aim of the study or those who do not agree with the inclusion

Date of first enrolment

01/07/2015

Date of final enrolment

30/09/2017

Locations

Countries of recruitment

Slovenia

Study participating centre

Department of Otorhinolaryngology and Cervicofacial Surgery, University Medical Centre

Ljubljana

Zaloska 2

Ljubljana

Slovenia

1000

Study participating centre

Institute of Oncology Ljubljana

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Slovenia

1000

Sponsor information

Organisation

Ljubljana University Medical Centre

ROR

<https://ror.org/01nr6fy72>

Organisation

Institute of Oncology Ljubljana

Funder(s)

Funder type

Government

Funder Name

Javna Agencija za Raziskovalno Dejavnost RS

Alternative Name(s)

Slovenian Research Agency, Javna agencija za raziskovalno dejavnost RS v angleškem jeziku: Slovenian Research Agency, Javna Agencija za Raziskovalno Dejavnost RS, The Slovenian Research and Innovation Agency (ARIS), Javna agencija za znanstvenoraziskovalno in inovacijsko dejavnost Republike Slovenije, ARRS, ARIS

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Slovenia

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available. The data will be held in an institutional electrochemistry database.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2016		Yes	No
Protocol file			30/08/2022	No	No
Protocol file			30/08/2022	No	No