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Treatment of gynecological cancers with chemotherapy delivered locally to the tumor site by electrical pulses

Submission date 23/02/2020	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 26/02/2020	**Overall study status** Ongoing	
Last Edited 25/08/2026	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
Electrochemotherapy is a local treatment modality with effectiveness comparable to other local ablation techniques. With electrochemotherapy 80% objective response can be achieved and is suitable for the treatment of different types of tumors. The method is based on increased drug delivery to cells previously exposed to electroporation. The most commonly used cytotoxic agents are bleomycin and cisplatin. The aim of the proposed clinical trial is to determine the efficacy, feasibility and safety of electrochemotherapy in the treatment of local or regional recurrences of gynecologic tumors in which standard treatment has been exhausted.

Who can participate?
Patients with local or regional recurrences of gynecologic tumors in which standard treatment has been exhausted.

What does the study involve?
All participants will be treated with electrochemotherapy. The procedure is standardized and is performed according to the published Standard Operating Procedure (SOP) for electrochemotherapy. The chemotherapy drug bleomycin is injected intravenously or intratumorally and cisplatin only intratumorally. Electric pulses will be delivered to the tumour in order to facilitate the entrance of chemotherapeutic drug into the cancer cells.

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?
Institute of Oncology Ljubljana (Slovenia)

When is the study starting and how long is it expected to run for?
April 2020 to June 2029

Who is funding the study?
Slovenian Research Agency, ARRS (Javna Agencija za Raziskovalno Dejavnost RS)

Who is the main contact?
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Additional identifiers

ClinicalTrials.gov (NCT)
NCT04760327

Study information

Scientific Title
Electrochemotherapy of gynecological cancers

Acronym
GynECT

Study objectives
Electrochemotherapy can be used to achieve local/regional tumor control and palliation of gynecologic tumors where standard treatment has been exhausted.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/1/2018, Republic of Slovenia National Medical Ethics Committee (Ministry of Health, Štefanova 5, SI-1000 Ljubljana, Slovenia; +386 1 478 69 13; kme.mz@gov.si), ref: 0120-692 /2017/4

Primary study design
Interventional

Study design
Institutional interventional phase II study

Study type(s)
Treatment

Health condition(s) or problem(s) studied

Gynecologic cancer

Interventions
Patients will be treated with electrochemotherapy according to Standard Operating Procedure (SOP) for electrochemotherapy. Intravenous or intratumoral bleomycin or intratumoral cisplatin will be used as described in SOP. The electric pulses will be delivered by electrodes to the tumors generated by electric pulse generator Cliniporator (IGEA, Carpi, Italy).

One time treatment, maximal duration of the procedure 30 minutes.

Follow up: 1, 3, 6, 9, 12,18, and 24 months after the electrochemotherapy.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Effectiveness will be measured by determined tumor volume according to RECIST (version 1.1) before the therapy and at each follow up: 1, 3, 6, 9, 12, 18, and 24 months after the therapy

Key secondary outcome(s)
Safety will be followed at each follow-up visit: 1, 3, 6, 9, 12, 18, and 24 months after the therapy, according to CTCAE criteria

Completion date
30/06/2029

Eligibility

Key inclusion criteria
1. Local or regional recurrences of gynecologic tumors in which standard treatment has been exhausted
2. Age over 18 years
3. Life expectancy of more than 3 months
4. Karnofsky body capacity ≥ 70 or <or 2 based on the WHO scale
5. At least 2 weeks have elapsed since the last possible treatment
6. The patient should be able to understand the treatment process and any side effects that may occur with the treatment
7. The patient must be able to sign inform consent to participate in the clinical study
8. Before entering the study, the patient must be presented at the multidisciplinary board
9. Suitable for procedures in anesthesia

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Lesions not suitable for treatment with electrochemotherapy (invasion of bone, infiltration of large vessels)
2. A life-threatening infection and/or heart failure and/or liver failure and/or other threatening systemic diseases
3. A significant decline in lung function that requires DLCO determination. We are not allowed to treat patients if DLCO is abnormal
4. Age under 18 years
5. Major disruptions in the coagulation system (which do not respond to the standard therapy – supplementation of vitamin K or freshly frozen plasma)
6. A previously received cumulative dose of bleomycin≥ 400 mg / m^2
7. A chronic decline in the kidney function (creatinine > 150 µmol/L)
8. Epilepsy
9. Pregnancy
10. The patients' uncapatibily of comprehending the purpose or course of the trial, or not agreeing to be included in the trial

Date of first enrolment
01/04/2020

Date of final enrolment
30/06/2027

Locations

Countries of recruitment
Slovenia

Study participating centre
Institute of Oncology Ljubljana
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Sponsor information

Organisation
Institute of Oncology Ljubljana

ROR
https://ror.org/00y5zsg21

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 will be stored in a non-publically available repository.

IPD sharing plan summary
Stored in repository