

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

Submission date 23/02/2020	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 26/02/2020	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 08/04/2024	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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 December 2025

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

Who is the main contact?
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Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number**ClinicalTrials.gov number**

NCT04760327

Secondary identifying numbers

Nil known

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

Study design

Institutional interventional phase II study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

No participant information sheet available

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 measure

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

Secondary outcome measures

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

Overall study start date

01/10/2017

Completion date

31/12/2025

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 ≤ 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 informed 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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

30

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 / m²
7. A chronic decline in the kidney function (creatinine > 150 μ mol/L)
8. Epilepsy
9. Pregnancy
10. The patients' incapability 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

01/07/2025

Locations

Countries of recruitment

Slovenia

Study participating centre

Institute of Oncology Ljubljana

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Sponsor information

Organisation

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Sponsor type

Hospital/treatment centre

Website

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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

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date

31/12/2026

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