ISRCTN78463063 https://doi.org/10.1186/ISRCTN78463063

EURECA (European research on electrochemotherapy in head and neck cancer) project

Submission date	Recruitment status	[_] Prospectively registered
10/03/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
17/03/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/06/2016	Cancer	

Plain English summary of protocol

Background and study aims
Electrochemotherapy (ECT) is a treatment to get chemotherapy into cancer cells. Firstly, a chemotherapy drug (for example, cisplatin or bleomycin) is injected into the tumour. An electric pulse is then applied, altering the outer layer of the cancer cell and making it easier for the drug to enter. ECT is used to control of recurrent or new skin or mucosal cancers in the head and neck region that are not suitable for chemoradiation or surgery. The aim of this study is to test the performance of ECT as an alternative to standard palliative treatments for head and neck cancers. It is hoped that it will work as well as the standard treatments but without as many side effects.

Who can participate?
Adults (aged over 18) with recurrent, metastatic or primary head and neck cancer not suitable for surgery or chemoradiotherapy.

What does the study involve?
Each eligible participant receives an intravenous (i.v.) or intratumoral (i.t.) administration of bleomycin (a drug used for chemotherapy) at a very low dosage and 8 min after the i.v. injection or immediately after the i.t. injection the tumor cells receive an electric stimulation with specific needle electrodes (the process is called electroporation). The procedure can be done under local or general anaesthesia according to the position and the numbers of tumors that have to be treated. The tumor response is investigated after two months and all the patients with complete healing of the lesions have visits at 4, 8 and 12 months after treatment.

What are the possible benefits and risks of participating?
Patients who will partially or totally respond to this treatment are likely to live longer and have a better quality of life (less pain, less bleeding, less anatomical or functional compromise).

Where is the study run from?
This study is run in 6 University or Major Head and Neck Departments in Italy (Pavia), Denmark (Copenhagen), Netherlands (Amsterdam), Spain (Barcelona), UK (London) and Slovenia (Lubljiana).

When is the study starting and how long is it expected to run for?
June 2011 to September 2015

Who is funding the study?
IRCCS Policlinico San Matteo Foundation (Italy)

Who is the main contact?
Dr Giulia Bertino
giulia.bertino@tin.it

Contact information

Type(s)
Scientific

Contact name
Dr Giulia Bertino

ORCID ID
https://orcid.org/0000-0003-2840-5184

Contact details
Dept. of Otolaryngology Head & Neck Surgery
University of Pavia
IRCCS Policlinico San Matteo Foundation
P.le Golgi 2
Pavia
Italy
27100
+39 (0)382 526 218
giulia.bertino@tin.it

Additional identifiers

Study information

Scientific Title
Local treatment of HN cancer by electrochemotherapy. Analysis of the efficacy of the procedure in tumor control and survival

Acronym
EURECA

Study objectives

The primary aim is the evaluation of tumor response (one target lesion) according to RECIST criteria (version 1.1) at 2 months follow-up; the secondary aims are the data evaluation about safety (toxicity) of the procedure, analysis of overall and progression free survival and quality of life. In case of execution of PET-CT another secondary aim will be the evaluation of PET-CT uptake change between pre treatment and 8 weeks post treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Bioethic Committee of the IRCCS Policlinico San Matteo Foundation, 24/11/2011, refs: 20110005216 & P-20110034090

Primary study design
Observational

Study design
Phase II observational study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Recurrent, metastatic HN cancer or primary cancer in patients with severe co-morbidities and/or which only regular treatment with extensive morbidity is available

Interventions
Collection of the data about tumor response, safety, toxicity, survival and quality of life (QoL) of patients submitted to intravenous administration of 15000 IU BLM/m2 within 1 min, after 8 min electroporation (with Cliniporator and specific electrodes) of the lesion with a 1 cm of safe margin. Procedure has to be finished within 30 min.

4 weeks after procedure:
1. CT or MRI (same imaging as pre-operative evaluation)
2. Evaluation of tumor response in accordance with RECIST criteria (version 1.1)
3. Photographic documentation
4. QOL assessments (EORTC QLQ-C30, EORTC QLQ-H&N35, EQ_5D)
5. In case of residual disease a second ECT can be considered (if residual disease after the 2nd ECT other treatment options must be considered).

8 weeks after procedure:
1. CT or MRI and PET-CT
2. Evaluation of tumor response in accordance with RECIST criteria (version 1.1)
3. Photographic documentation
4. QOL assessments (EORTC QLQ-C30, EORTC QLQ-H&N35, EQ_5D)
5. Biopsy on indication
6. In case of residual disease a second ECT can be considered (if residual disease after the 2nd ECT other treatment options must be considered).
7. All the CR must be followed up at 4, 8, 12 months after treatment

Intervention Type
Procedure/Surgery

Primary outcome(s)
Evaluation of tumor response (only one target lesion) at 2 months after the procedure

Key secondary outcome(s)
1. Safety (toxicity) of the procedure
2. Analysis of overall and progression free survival
3. “Quality of life” (EORTC QLQ-C30, EORTC QLQ-H&N35, EQ_5D)

The evaluation of the secondary aims will be performed at each follow-up visit till one year of follow up in case of complete responders or till the last follow up visit before exit the protocol in case of partial responders, stable or progressive disease or death or patient unwilling/unable to continue follow-up.

Completion date
30/09/2015

Eligibility

Key inclusion criteria
1. Histologically verified cancer of any type
2. Progressive and/or metastatic disease
3. Primary disease not eligible for surgery for patient’s general conditions or for the need of extensive surgery
4. Patients must have offered standard treatments
5. Measurable lesions suitable for application of electric pulses
6. Age> 18 yrs
7. Performance status (Karnofsky ≥ 70; WHO ≤ 2)
8. Life expectancy> 3 months
9. Treatment free interval of at least 4 weeks after previously applied chemo- or radiotherapyto the target lesions
10. Patients must be mentally capable of understanding the information given and sign informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Other symptomatic lesions not under control
2. Lesions not suitable for ECT (bony invasion, large vessels infiltration, etc.)
3. Acute lung infection
4. Symptoms of poor lung function necessitates DLCO and patient can not be treated if this is abnormal
5. Severe coagulation disorders not correctable
6. Previous allergic reactions to bleomycin
7. If cumulative dose of 240000 IU BLM/m2 was previously exceeded
8. Chronic renal dysfunction (creatinine> 150 µmol/L)
9. Pregnancy or lactation

Date of first enrolment
01/11/2011

Date of final enrolment
30/09/2015

Locations

Countries of recruitment
United Kingdom

England

Denmark

Italy

Netherlands

Slovenia

Spain

Study participating centre
Department of Otolaryngology Head & Neck Surgery, University of Pavia, IRCCS Policlinico San Matteo Foundation
P.le Golgi 2
Pavia
Italy
27100

Study participating centre

Dept. of Otolaryngology, Head and Neck Surgery, VU University Medical Center
Amsterdam
Netherlands
1007 MB

Study participating centre
Oncologic Service Hospital Clinic
Barcelona
Spain
-

Study participating centre
Dept. of Oncology, Dept. of Otolaryngology, Head Neck Surgery, Copenhagen University Hospital
Copenhagen
Denmark
2100

Study participating centre
Dept. of Maxillofacial/Head Neck Surgery Royal Marsden Hospital
London
United Kingdom
SW3 6JJ

Study participating centre
Dept. of Otolaryngology, University Clinical Center Institute of Oncology
Ljubliana
Slovenia
SI - 1000

Sponsor information

Organisation
IRCCS Policlinico San Matteo Foundation (Italy)

ROR
https://ror.org/05w1q1c88

Funder(s)

Funder type
Research organisation

Funder Name
IRCCS Policlinico San Matteo Foundation (Italy)

Results and Publications

Individual participant data (IPD) sharing plan

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	01/08/2016		Yes	No