

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

Submission date 10/03/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 17/03/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 10/06/2016	Condition category Cancer	<input type="checkbox"/> Individual participant data

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 (Ljubljana).

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

<http://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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

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

Study design

Phase II observational study

Primary study design

Observational

Secondary study design

Longitudinal study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

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 measure

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

Secondary outcome measures

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.

Overall study start date

15/06/2011

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 \geq 70; WHO \leq 2)

8. Life expectancy > 3 months
9. Treatment free interval of at least 4 weeks after previously applied chemo- or radiotherapy to the target lesions
10. Patients must be mentally capable of understanding the information given and sign informed consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

120

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**

Denmark

England

Italy

Netherlands

Slovenia

Spain

United Kingdom

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

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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
Ljubljana
Slovenia
SI - 1000

Sponsor information

Organisation

IRCCS Policlinico San Matteo Foundation (Italy)

Sponsor details

c/o Prof. Marco Benazzo
Dept. of Otolaryngology Head & Neck Surgery
University of Pavia
IRCCS Policlinico San Matteo Foundation
P.le Golgi 2
Pavia
Italy
27100

Sponsor type

Hospital/treatment centre

Website

<http://www.sanmatteo.org>

ROR

<https://ror.org/05w1q1c88>

Funder(s)

Funder type

Research organisation

Funder Name

IRCCS Policlinico San Matteo Foundation (Italy)

Results and Publications

Publication and dissemination plan

Intention to publish results of the EURECA protocol for skin cancer for the end of 2015 and for mucosal cancer for 2016.

Intention to publish date

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