Trial record **1 of 1** for: eortc 1219

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AF CRT +/- Nimorazole in HNSCC

This study is currently recruiting participants.

See Contacts and Locations

Verified June 2017 by European Organisation for Research and Treatment of Cancer - EORTC

Sponsor:
European Organisation for Research and Treatment of Cancer - **EORTC**

Collaborator:
Danish Head and Neck Cancer Group

Information provided by (Responsible Party):
European Organisation for Research and Treatment of Cancer - EORTC

ClinicalTrials.gov Identifier:
NCT01880359

First received: June 12, 2013
Last updated: June 12, 2017
Last verified: June 2017
History of Changes

Full Text View | **Tabular View** | **No Study Results Posted** | Disclaimer

How to Read a Study Record

Purpose

The drug nimorazole belongs to a class of chemicals known as 5-nitroimidazoles. Drugs from this class are used against infection. In addition, nimorazole makes tumor cells more sensitive to radiotherapy.

Therefore, the investigators want to find out whether the addition of nimorazole to the standard treatment with radiotherapy in combination with chemotherapy with cisplatin shows activity against your type of head and neck cancer and is safe.

Furthermore the investigators will investigate if a specific examination done with your tumor tissue will help to predict whether the treatment will work or not.

To find out if the activity observed with this treatment is not caused by chance alone, the investigators need to obtain data from patients who receive this treatment and from patients who receive other treatments.

The data from these two groups of patients will be compared to see which treatment is better.

Participants will be split into 2 groups. Each group will receive different treatments. The treatment each group receives is determined by chance using a computer program. This works like flipping a coin and is called randomization. This helps to make sure that groups of patients are similar when the study starts. Neither you, your study doctor, nor the study staff can influence in which group you will be placed or which treatment you will receive.

If allocated to group 1, Patient will receive radiotherapy in combination with chemotherapy with cisplatin and nimorazole as a pill. This is considered the 'experimental' treatment.

If allocated to group 2, patient will receive radiotherapy in combination with chemotherapy with cisplatin and a so called 'placebo' as a pill. The placebo is a dummy treatment. It looks like the real one, but it is not. It contains no active ingredient/medicine.

Condition	Intervention	Phase
Locally Advanced Head and Neck HPV Negative Squamous Cell Cancers	Drug: Cisplatin Radiation: Radiotherapy Drug: Placebo Drug: Nimorazole	Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Intervention Model: Parallel Assignment
Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)
Primary Purpose: Treatment

Official Title: A Blind Randomized Multicenter Study of Accelerated Fractionated Chemo-radiotherapy With or Without the Hypoxic Cell Radiosensitizer Nimorazole (Nimoral), Using a 15-gene Signature for Hypoxia in the Treatment of Squamous Cell Carcinoma of the Head and Neck.

Resource links provided by NLM:

Genetics Home Reference related topics: head and neck squamous cell carcinoma

Drug Information available for: Cisplatin

U.S. FDA Resources

Further study details as provided by European Organisation for Research and Treatment of Cancer - EORTC:

Primary Outcome Measures:

- locoregional control rate [Time Frame: 9 years after first patient in]

Secondary Outcome Measures:

- Time to distant metastasis [Time Frame: 9 years after first patient in]
- Time to second cancer [Time Frame: 9 years after first patient in]
- Overall survival [Time Frame: 9 years after first patient in]
- Disease-specific free survival [Time Frame: 9 years after first patient in]
- Acute and late morbidity [Time Frame: 9 years after first patient in]

Estimated Enrollment:	640
Study Start Date:	July 2014
Estimated Study Completion Date:	December 2020
Estimated Primary Completion Date:	May 2019 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Placebo Comparator: Radiotherapy+ Cisplatin+ Placebo Accelerated radiotherapy (Therapeutic Planning Target Volume (PTV): 70 Gray (Gy), 6 fractions/week, 35 fractions of 2 Gy, prophylactic PTV: 54.25 Gy, 6 fractions/week, 35 fractions of 1.55 Gy) + concomitant cisplatin (weekly schedule of 40mg/m2 (delivered on day 1, 8, 15, 22, 29) Patients will receive placebo (1.2 g/m2) 90 min (+/- 30 min) prior to each radiotherapy fraction but no more than 5 times a week (If the 6th radiotherapy fraction in a week is given on a separate day from the 5th fraction of radiotherapy, no nimorazole/placebo dose is received that day. If the 6th fraction of radiotherapy is given on the same day as the 5th fraction, nimorazole/placebo is given 90 minutes before the 5th radiotherapy fraction, only).	Drug: Cisplatin Radiation: Radiotherapy Drug: Placebo
Experimental: Radiotherapy+ Cisplatin+ Nimorazole Accelerated radiotherapy (Therapeutic PTV: 70 Gy, 6 fractions/week, 35 fractions of 2 Gy, prophylactic PTV: 54.25 Gy, 6 fractions/week, 35 fractions of 1.55 Gy) + concomitant cisplatin (weekly schedule of 40mg/m2 (delivered on day 1, 8, 15, 22, 29) . Patients will receive nimorazole (1.2 g/m2) 90 min (+/- 30 min) prior to each radiotherapy fraction but no more than 5 times a week (If the 6th radiotherapy fraction in a week is given on a separate day from the 5th fraction of radiotherapy, no nimorazole/placebo dose is received that day. If the 6th fraction of radiotherapy is given on the same day as the 5th fraction,	Drug: Cisplatin Radiation: Radiotherapy Drug: Nimorazole

nimorazole/placebo is given 90 minutes before the 5th radiotherapy fraction, only).	

Eligibility

Ages Eligible for Study:	18 Years and older (Adult, Senior)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Newly diagnosed tumors classified as stage III-IV located in the larynx, oropharynx and hypopharynx (unknown primary should be excluded; oral cavity are not eligible)
- Human papillomavirus(HPV)/p16 negative (≤70% positively stained cells), assessed locally for tumors of the oropharynx
- Tumors of the larynx and hypopharynx regardless of the HPV status
- Histopathological diagnosis of invasive squamous cell carcinoma in the primary tumor
- World Health Organization (WHO) performance 0-2
- All Hematology and biochemical investigations, should be done within 4 weeks before randomization (maximum 6 weeks before treatment starts)
- Normal bone marrow function based on routine blood samples, i.e. neutrophils ≥ 1.0 x 109/L, platelets ≥ 75 x 109/L, hemoglobin ≥ 10.0 g/dL or 6.2 mmol/L
- Normal kidney function creatinine clearance ≥ 60ml/min, and Electrolyte balance: calcium ≤ 11.5 mg/dl or 2.9 mmol/l, magnesium ≥ 1.2 mg/dl or 0.5 mmol/l
- Normal liver function assessed by routine laboratory examinations, i.e. bilirubin < 1.5 x Upper Limit of Normal (ULN), Aspartate aminotransferase (AST)< 3 x ULN, alkaline phosphatases < 3 x ULN
- No prior or current anticancer treatment to the head and neck area (e.g. radical attempted or tumor reductive surgery, neo-adjuvant chemotherapy, Epidermal Growth Factor Receptor (EGFR) inhibitors or radiotherapy).
- Patients must be candidate for curative intent external beam chemo-radiotherapy, and must be expected to complete the treatment.
- All patients should have an oral and dental examination including preferably clinical and radiological examination. Whenever indicated, extraction of dental elements should be carried out at least 10 days before treatment start;for 1-2 (max 2) monoradicular single tooth extractions (if not continous a max of 4) without bone resection 5 days (as a minimum) are allowed.
- Radiotherapy planned to start within acceptable delay (preferably within 2 weeks and a maximum of 4 weeks from randomization).
- Radiotherapy planned to start within 8 weeks from baseline imaging tumor assessment.
- Absence of any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule; those conditions should be discussed with the patient before randomization in the trial

- All subjects must agree to abstain from donating blood while receiving therapy and for four weeks following discontinuation of therapy.
- All subjects must agree not to share study medication with another person and to return all unused study drug to the investigator.
- Before patient registration, written informed consent must be given according to International Conference on Harmonisation /Good Clinical Practice (ICH/GCP), and national/local regulations (including material acquisition for central testing of the hypoxic signature)

Exclusion Criteria:

- Patients who have received treatment with any investigational drug substance within 4 weeks prior to randomization;
- Current participation in any other interventional clinical study;
- Pregnant or breast-feeding female patient. Pregnancy test should be done within 72 hours from treatment start;
- Female subjects of childbearing potential (defined as a sexually mature woman who 1) has not undergone a hysterectomy or bilateral oophorectomy or 2) has not been naturally post-menopausal (amenorrhoea following cancer therapy does not rule out childbearing potential) for at least 12 consecutive months (i.e. has had menses at any time in the preceding 12 consecutive months)) not willing to use adequate contraception during study and for 6 month after last dose of study drug;
- Male subjects not willing to use condoms throughout study drug therapy, and for 6 months after cessation of study therapy if their partner is of childbearing potential and has no contraception;
- Known or suspected HIV infection;
- Second malignancies in the 3 years prior to study entry with the exception of surgically cured carcinoma in situ of the cervix, in situ breast cancer, incidental finding of stage T1a or T1b prostate cancer, and basal/squamous cell carcinoma of the skin;
- Uncontrolled or chronic bacterial, fungal or viral infection;
- Known or suspected hypersensitivity to component(s) of investigational product or cisplatin contraindication;
- All indicated timelines and absolute values requested by the eligibility criteria must be adhered to. However, a maximum of +/- 10% of the reference value for laboratory parameters and a maximum of +/- 3 days for timelines may be acceptable. Discussion with EORTC Headquarters and study coordinator is encouraged.

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT01880359

Contacts

Contact: Dominiek Staelens, PhD dominiek.staelens@eortc.be

Contact: General study email adress 1219@eortc.be

Locations

Australia

Royal Brisbane And Women's Hospital
Brisbane, Australia, QLD 4029

Princess Alexandra Hospital - University Of Queensland
Brisbane, Australia, QLD 4102

Royal North Shore Hospital
St Leonards, Australia, NSW 2065

Calvary Mater Newcastle
Waratah, Australia, NSW 2298

Belgium

Hopitaux Universitaires Bordet-Erasme - Institut Jules Bordet
Brussels, Belgium, 1000

Cliniques Universitaires Saint-Luc
Brussels, Belgium, 1200

U.Z. Leuven - Campus Gasthuisberg
Leuven, Belgium, 3000

France

Centre Jean Perrin
Clermont-Ferrand, France, 63011

Centre Georges-Francois-Leclerc
Dijon, France, 21079

CHU de Tours - Hopital Bretonneau
Tours, France, 37044

Institut Gustave Roussy
Villejuif, France, 94805

Germany

Charite - Universitaetsmedizin Berlin - Campus Virchow-Klinikum
Berlin, Germany

Heinrich-Heine Universitaetsklinik Dusseldorf
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Ludwig-Maximilians-Universitaet Muenchen - Klinikum der Universitaet Muenchen - Campus Gross
Muenchen, Germany, 81377

Netherlands

Vrije Universiteit Medisch Centrum
Amsterdam, Netherlands, 7007MB

Radboud University Medical Center Nijmegen

Poland

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Gdansk, Poland, 80 211

The Great Poland Cancer Centre
Poznan, Poland, 61 866

Maria Sklodowska-Curie Memorial Cancer Centre
Warsaw, Poland

Lower Silesian Oncology Centre
Wrocław, Poland

Switzerland

Hôpitaux universitaires de Genève - HUG - site de Cluse-Roseraie
Geneva, Switzerland, 1211

UniversitaetsSpital Zurich
Zurich, Switzerland, 8091

Sponsors and Collaborators

European Organisation for Research and Treatment of Cancer - **EORTC**

Danish Head and Neck Cancer Group

Investigators

Study Chair: Jens Overgaard Aarhus University Hospital

Study Chair: Vincent Grégoire Cliniques Universitaires St. Luc

More Information

Responsible Party:	European Organisation for Research and Treatment of Cancer - EORTC
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Other Study ID Numbers:	**EORTC-1219**
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Additional relevant MeSH terms:

Neoplasms, Squamous Cell	Nimorazole
Carcinoma, Squamous Cell	Antineoplastic Agents
Neoplasms, Glandular and Epithelial	Antitrichomonal Agents
Neoplasms by Histologic Type	Antiprotozoal Agents
Neoplasms	Antiparasitic Agents
Carcinoma	Anti-Infective Agents
Cisplatin	

ClinicalTrials.gov processed this record on August 22, 2017