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Chemotherapy with paclitaxel and capecitabine for the treatment of recurrent or metastatic head and neck cancer

Submission date
22/03/2018

Recruitment status
No longer recruiting

Registration date
06/04/2018

Overall study status
Completed

Last Edited
01/04/2019

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The aim of this phase II study was to evaluate the anticancer activity and sifde effects of paclitaxel and capecitabine, a chemotherapy regimen (sequence of medicines) that does not contain any platins (platinum-containing anticancer drugs), in patients with recurring or spreading cancer in the head and neck. People with this cancer have generally poor outcomes - when this study was started patients with this condition could in average only hope to live for 6-8 months. The most common regimen at that time was a combination of the two drugs cisplatin and 5-FU. That was the standard offer to our patients as well, but as it is also a very toxic drug combination, especially to these often very fragile patients, we were looking for a drug combination that is less toxic and as effective or more effective against cancer. A combination of paclitaxel and capecitabine produced fewer or less serious side effects in breast cancer patients, so we thought it could be interesting to test this regimen in head and neck cancer patients.

Who can participate?
Men or women aged 18-75 years with recurring or spreading head and neck cancer that can not be treated with surgery or radiotherapy.

What does the study involve?
All patients received paclitaxel via a vein and capecitabine by mouth, with each treatment cycle involving 14 days of treatment and 7 days with no treatment.

What are the possible benefits and risks of participating?
Treatment might extend life. The medicines might cause side effects.

Where is the study run from?
Department of Oncology, Herlev Hospital, Denmark.

When is the study starting and how long is it expected to run for?
The study ran from September 2000 to December 2008.

Who is funding the study?
The study was funded by the trial investigators.

Who is the main contact?
Dr Jens Bentzen, jeben@regionh.dk.

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HH 0310

Study information

Scientific Title
Phase II analysis of paclitaxel and capecitabine in the treatment of recurrent or disseminated squamous cell carcinoma of the head and neck region

Study objectives
The aim of this phase II study was to evaluate the antitumor activity and toxicity of a non-platin-containing regimen with paclitaxel and capecitabine for patients with disseminated or recurrent head and neck cancer

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study was approved by the Ethics Committees of Copenhagen, 23/07/1999, (KF) 02-046/99

Study design
Non-randomised trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Recurrent or disseminated squamous cell carcinoma of the head and neck

Interventions
The treatment plan was as follows:
Day 1: Paclitaxel 175 mg/m2 iv over 3 h
Days 1 to 14: Capecitabine 825 mg/m2 per dose orally bid (twice daily) for 2 weeks, with 200 ml water taken <30 min after a meal
After a 1-week interval without medication, the treatment was repeated. The patients received the following iv premedication 30 min before administration of paclitaxel: dexamethasone 10 mg, clemastine 2 mg, and nizatidine 100 mg.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Paclitaxel and capecitabine

Primary outcome measure
1. Response rate as defined by WHO Handbook for Reporting Results of Cancer Treatment. Patients were only eligible if they had at least one lesion measurable in two dimensions using Ultasound, MRI scan or CT-scan. Lesions were measured at baseline and after every 3 cycles (every 9th week).
2. Toxicity was measured by blood samples and patient interview after every treatment.

Secondary outcome measures
1. Overall survival was measured from the day chemotherapy started until death.
2. Compliance was measured as number of treatment cycles given at 100% dose and number of treatments given without toxicity-related delay.

Overall study start date
01/09/2000

Completion date
31/12/2008

Eligibility

Key inclusion criteria
1. Histologically confirmed recurrent or disseminated squamous cell carcinoma of the head and neck region, not suitable for curative radiotherapy or salvage surgery
2. Measurable disease in minimum 2 dimensions
3. Aged 18-75 years
4. World Health Organization (WHO) performance status <=2
5. No previous chemotherapy for 1 month
6. No other severe life-shortening disease or other malignant disease
7. Adequate bone marrow, liver, and renal function

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
The study aimed to treat 50 patients in order to evaluate response rates and toxicity for the two-drug combination. As the study result was promising, an additional 133 patient were enrolled.

Key exclusion criteria
1. Non-measurable disease
2. Pregnant or breastfeeding women
3. Chemotherapy within the last month
4. Brain metastases
5. Other malignant disease

Date of first enrolment
01/09/2000

Date of final enrolment
31/12/2008

Locations

Countries of recruitment
Denmark

Study participating centre
Department of Oncology, Herlev Hospital, Denmark.
Herlev
Denmark
2730

Study participating centre
Department of Oncology, The Finsen Centre, Rigshospitalet
Copenhagen
Denmark
2100

Study participating centre
Department of Oncology, Aarhus University Hospital, Denmark.
Aarhus
Denmark
8000

Sponsor information

Organisation
Department of Oncology, Herlev Hospital

Sponsor details
Herlev Ringvej 75
Herlev
Denmark
2730

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00wys9y90

Funder(s)

Funder type
Not defined

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
The results based on the first 50 patients included were published in 2007 (HEAD & NECK—DOI 10.1002/hed January 2007). The extended study included 183 patients. The final results are now ready for publication and the paper has been submitted.

Intention to publish date

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results from first 50 patients	01/01/2007		Yes	No
Participant information sheet			01/04/2019	No	Yes