A randomized phase II study to evaluate the efficacy and safety of chemotherapy (CT) vs androgen deprivation therapy (ADT) in patients with recurrent and/or metastatic, androgen receptor (AR) expressing, salivary gland cancer (SGCs)

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The two main objectives of the study are:* To assess the efficacy of ADT in treatment naïve patients with recurrent and/or metastatic, androgen receptor (AR) expressing, SGCs. The primary measure of efficacy is Progression-Free Survival (PFS).* To...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Soft tissue neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON54823

Source
ToetsingOnline

Brief title
EORTC-1206-HNCG

Condition

- Soft tissue neoplasms malignant and unspecified

Synonym
salivary duct carcinoma

Research involving

Human

Sponsors and support

Primary sponsor: European Organisation for Research in Treatment of Cancer (EORTC)
Source(s) of monetary or material Support: EORTC financiert de METC indiening

Intervention

Keyword: androgen deprivation therapy, chemotherapy, recurrent or metastastic disease, salivary gland cancer

Outcome measures

Primary outcome

Cohort A (treatment naïve patients):

Progression-Free Survival according to Response Evaluation Criteria In Solid

Tumors (RECIST) criteria version 1.1 and/or Prostate Cancer

Clinical Trials Working Group (PCWG2) (2007) for bone lesions, or death,

whichever comes first.

Cohort B (pretreated patients):

Best Overall Response defined according to RECIST v 1.1.

Secondary outcome

For treatment-naïve patients:

- Best Overall Response defined according to RECIST v 1.1

- Overall Survival

- Toxicity

For pre-treated patients:

- Progression Free Survival

- Overall Survival

- Toxicity

Study description

Background summary

Salivary Gland Cancer (SGC) are rare tumors that comprise less than 5% of all cancers of the head and neck. The subtype of SGC in this study, expresses androgen receptors (AR) on the cell surface, which can be used as a therapy treatment. The anti-androgen treatment (treatment directed against the AR) in this study is a combination of two agents: bicalutamide and triptorelin. This combination is the standard treatment of prostate cancer with expression of AR. In this study we compare the effects of anti-androgen therapy with chemotherapy to investigate which treatment shows the best results. In this study we also examine various mechanisms at the cellular level which may explain why the tumor is or is not responding to treatment.

Study objective

The two main objectives of the study are:
* To assess the efficacy of ADT in treatment naïve patients with recurrent and/or metastatic, androgen receptor (AR) expressing, SGCs. The primary measure of efficacy is Progression-Free Survival (PFS).
* To describe the effect of ADT in pretreated patients with recurrent and/or metastatic, AR expressing SGCs. The main measure of efficacy is response to treatment.

Study design

Approximately 220 patients will participate in Europe, Based on their previous treatment, patients will be allocated to one of the two groups of study.
Patients who previously had chemotherapy will receive anti-androgen treatment.
The patients who had not been treated before will be randomized between anti-androgen treatment or standard chemotherapy. This standard chemotherapy may be cisplatin together with carboplatin or doxorubicin together with paclitaxel. The chemotherapy will be administered for up to 6 cycles or until tumor growth or the occurrence of limiting side effects.
If a patient has received chemotherapy and the tumor is progressive, it can be switched to anti-androgen therapy.

Intervention

Patients who previously had chemotherapy will receive anti-androgen treatment.
The patients who had not been treated before will be randomized between

anti-androgen treatment or standard chemotherapy. This standard chemotherapy may be cisplatin together with carboplatin or doxorubicin together with paclitaxel.

Study burden and risks

This research may lead to new treatment options for patients with salivary gland cancer with metastases or local recurrence of the disease. In addition, this study results in new information that may lead to new tools for further research.

Because most of all investigation are part of the normal practice, the extend of the burden for the patients will be minimal.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

-Histologically proven diagnosis of recurrent and/or metastatic salivary duct cancer; adenocarcinoma NOS; and AR expression level of =6 in nuclei of neoplastic cells based on central review
-Presence of at least one uni-dimensional measurable lesion by CT-scan or MRI according to RECIST criteria version 1.1 (target lesion).
-Patients older than 18 years old;
-Performance Status ECOG 0-1;

Exclusion criteria

-active second malignancy during the last five years
-Patients who received vaccine for yellow fever
-cardiac abnormalities

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-09-2015
Enrollment:	1
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Bicalutamide
Generic name:	Bicalutamide
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Carboplatin
Generic name:	Carboplatin
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Cisplatin
Generic name:	Cisplatin
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Doxorubicin
Generic name:	Doxorubicin
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Paclitaxel
Generic name:	Paclitaxel
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	12-02-2015
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	27-07-2015
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	25-02-2016

Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	29-02-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	28-10-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	15-12-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	06-03-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	07-04-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	07-10-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	03-11-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	27-01-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	28-02-2023

Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2013-000314-38-NL
ClinicalTrials.gov	NCT01969578
CCMO	NL51577.091.14