Antiviral therapy (cidofovir, an acyclic nucleoside phosphate) in combination with radiotherapy in HPV-positive tumors of the oropharynx

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27994

Source
NTR

Brief title
Antrhox

Health condition

Carcinoma
Oropharynx
Radiotherapy

Sponsors and support

Primary sponsor: initiator = sponsor
Source(s) of monetary or material Support: fund = initiator

Intervention

Outcome measures

Primary outcome

1. Primary objective: determining maximum tolerated dose of cidofovir in combination with radiotherapy.

Secondary outcome

2. Secundary objective: observation of tumor response by means of changement of HPV, p16 and p53 activity and by PET-CT scanning on tumoral gross volume 3 weeks before and after treatment.

Study description

Study objective

1. Primary objective: determining maximum tolerated dose of cidofovir in combination with radiotherapy.

2. Secundary objective: observation of tumor response by means of changement of HPV, p16 and p53 activity and by PET-CT scanning on tumoral gross volume 3 weeks before and after treatment.

Study design

Starting one week before radiotherapy and weekly continuing adminstration of cidofovir for six weeks.

Pet-CT scan after three months, Assessment of cohort untill four weeks after the last administration.

Intervention

Additional adminsitration of cidofovir during the six weeks of radiotherapeutical treatment.
Extra biopsy after 96 hours of the first cidofovir administration, if feasible.
Monitoring urine and serum for renal, liver function, full blood count weekly and monitoring vital parameters weekly during administration.

Contacts

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Eligibility criteria

Inclusion criteria

1. Histological proven HPV-positive carcinoma of the oropharynx in the dose escalating schedule.

2. UICC TNM I-IV, for which curable (high dosing) radiotherapy is advised.

3. WHO performance status 0-4

Exclusion criteria

1. More then 10% weight loss the last 6 months.

2. Abnormal serum bilirubin, white blood cells, neutrophils, platelets, hemoglobin.

3. Prior history of head or neck radiotherapy.

4. Uncontrolled infectious disease.

5. Unwilling and unable to comply with the study prescriptions.

6. Presence 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 registration in the trial.

Study design

Design

Study type:	Interventional
Intervention model:	Other

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2009
Enrollment:	12
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 33865
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL1396
NTR-old	NTR1456

Register	ID
CCMO	NL19517.068.07
ISRCTN	ISRCTN wordt niet meer aangevraagd
OMON	NL-OMON33865

Study results