Efficacy and Cost Efficacy of Prophylactic treatment with Antibiotics during concomitant chemoradiotherapy in patients with locally advanced head and neck cancer to prevent Aspiration Pneumonia. A randomized phase II-III study

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To observe a decrease in number of definite and/or suspected pneumonia after prophylactic treatment with antibiotics during CRT in patients with LAHNC.To observe a decrease in the number of admissions in the hospital To observe a decrease in the…

Ethical review	Approved WMO
Status	Pending
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Interventional

Summary

ID

NL-OMON39949

Source
ToetsingOnline

Brief title
PANTAP

Condition

- Miscellaneous and site unspecified neoplasms benign

Synonym
inhalation pneumonia

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: antibiotics, chemoradiotherapy, locally advance head and neck cancer, prevention

Outcome measures

Primary outcome

The primary outcome for the study will be the number of definite pneumonia and/

or suspected pneumonia.

Secondary outcome

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Study description

Background summary

Concomitant chemoradiotherapy (CRT) is used in locally advanced head and neck cancer (LAHNC). It will be administered to patients for unresectable disease or for organ preservation as primary treatment. Furthermore, it can be used as postoperative treatment in case high risk recurrent disease is present.(1) This treatment induces a high rate of acute toxicity, such as mucositis, dermatitis, dysphagia, anorexia, and pain.(2) Swallowing dysfunction and aspiration are seen in a high proportion (30%-100%) of patients and with an immense impact on Quality of life (QoL).(3;4) Around half of the patients will develop an aspiration pneumonia during or shortly after the treatment.

Patients, who develop fever during concomitant chemoradiotherapy, are most of the time admitted in the hospital. In the differential diagnosis pneumonia is on the first place in all those patients. The standard diagnostic procedures consist of a chest X-ray and culture of the sputum and blood. Pneumonia can lead to mortality in this frail patient group.(5;6) The treatment of patients treated with chemoradiotherapy who develop fever and have a definite or

suspected pneumonia, is administration of antibiotics, most frequently intravenous amoxicillin/clavulanic acid.

LAHNC patients who are smoking and/or with malnutrition are at the highest risk of getting a pneumonia during or after radiotherapy.(7) Because smoking is one of the risk factors of developing head and neck cancer chronic obstructive pulmonary disease (COPD) is frequently present in this group. Also, COPD is a known risk factor for developing pneumonias.
Aspiration is seen in all primary sites of head and neck cancer (8), sometimes it is seen more frequently in patients with cancer of the larynx and hypopharynx.(9)

No data of prophylactic administration of antibiotics are available in LAHNC patients. However, a Cochrane review was published to assess the effects of prophylactic antibiotic regimens for the prevention of respiratory tract infections (RTIs) and overall mortality in adults receiving intensive care. There was a significant reduction in both RTIs (number of studies = 16, odds ratio (OR) 0.28, 95% confidence interval (CI) 0.20 to 0.38) and total mortality (number of studies = 17, OR 0.75, 95% CI 0.65 to 0.87) in the treated group.(10)

In this study (PANTAP study) we want to investigate the efficacy and the cost efficacy of administration of prophylactic antibiotics during CRT in patients with LAHNC to prevent aspiration pneumonia.

Study objective

To observe a decrease in number of definite and/or suspected pneumonia after prophylactic treatment with antibiotics during CRT in patients with LAHNC.
To observe a decrease in the number of admissions in the hospital
To observe a decrease in the number of days of admission in the hospital
To measure Quality of life (QoL)
To investigate the effects on mortality To observe side effects of amoxicillin clavulanic acid
To observe causative agents, including amoxicillin-clavulanic acid resistant, of infections at other sites during follow-up (3.5 months after the end of CRT)

Study design

A randomized phase II-III, open label study

Intervention

Prophylactic treatment
Amoxicillin/clavulanic acid suspension

625 mg tid start day 29 until 2 weeks after CRT

Study burden and risks

All patients will receive treatment conform current standards. Although the experimental arm will receive amoxicillin/clavulanic acid tid which is supposed to decrease the number of definite and/ or suspected pneumonia in LAHNC patients treated with CRT. Amoxicillin/clavulanic acid will probably not lead to extra toxicity.

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

Patients with LAHNC which will be treated with CRT as discussed by a multidisciplinary team (i.e. a head and neck surgeon, a medical oncologist, and a radiation oncologist). This can be CRT as primary treatment or postoperative CRT.
Written informed consent
Expected adequacy of follow-up

Exclusion criteria

Patients with pneumonia within the last 14 days before day 29 of CRT
Patients with other infections within the last 14 days before day 29 of CRT
Patients with use of maintenance antibiotics
Patients with antibiotic treatment within the last 14 days before day 29 of CRT
Patients with an allergy on amoxicillin

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:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2011
Enrollment:	106
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Augmentin

Generic name:	amoxicillin/clavulanic acid
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	24-05-2011
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	15-11-2011
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	15-12-2011
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	24-01-2012
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	28-03-2012
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	13-07-2012
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	12-11-2012
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	25-04-2014
Application type:	Amendment

Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	28-04-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	30-04-2014
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	EUCTR2011-000076-33-NL
CCMO	NL35970.091.11