Oropharyngeal and intestinal microbiota: important factors in prevention or acquisition of nosocomial infections in patients admitted to the ICU after major elective surgery: an explorative pilot

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hepatobiliary neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON40960

Source
ToetsingOnline

Brief title
Role of microbiota in nosocomial infections

Condition

- Hepatobiliary neoplasms malignant and unspecified

Synonym
Infection, prevention

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W,Healthy Ageing Pilot

Intervention

Keyword: Highly Resistant Microorganisms, Microbiota, Nosocomial, Oral health

Outcome measures

Primary outcome

The objective of this observational pilot is the evaluation of incidence of HSMO- and HRMO-carriage, evaluation of oral and gut flora before, during and after hospitalization and evaluation of health status related to an ecological niche of these micro-organisms (oral cavity). Therefore, cultures taken by study protocol will be recorded, along with surveillance cultures taken by standard protocol and whole microbiome analysis. Oral health will be assessed using a standardized scale (Dutch Periodontal Screening Index -DPSI- Addendum I and Decayed Missing Filled Teeth Index (DMFT).
Also, Post-Operative Wound Infections (POWIs), including mediastinitis and bacteremias will be recorded, as well as causative micro-organism(s) and time to diagnosis of infection from day of hospitalization. Additional outcome measures will be: Length of Stay (LOS) in hospital and ICU, duration of mechanical ventilation, duration of central line(s) in situ, antibiotic use from time of hospitalization until 8 weeks after admission, re-admission(s) to the ICU and indication for re-admission, re-exploration(s) and indication for re-exploration, quality of life (QOL) using a standardized scale before surgery

and on post-discharge follow-up, and mortality until one year after inclusion.

Further, the study log will contain anonymous demographic and clinical data of study subjects recorded on inclusion and during the study period.

Associations between SAO (including mortality, bacteremia, POWI, longer (>= 4 days of stay in ICU and/ or mechanical ventilation) with baseline characteristics such as HRMO-carriage, oral health will be studied, as well as SAO in association with QOL.

Incidence of colonization with specific micro-organisms such as Methicillin-susceptible and resistant S.aureus, Vancomycin-Resistant Enterococci (VRE), Gram-negatives, including HRMOs will be studied in association with baseline characteristics such as oral health, age. Duration of HRMO-carriage will be evaluated.

Secondary outcome

Zie hierboven, Primary study parameters/outcome of the study

Study description

Background summary

Colonization with bacteria and associated prevention or acquisition of nosocomial infections are important issues in critical care patients after major elective surgery. Health-care associated infections lead to higher antibiotic use inducing more antimicrobial resistance, higher mortality, longer length of stay and greater costs. A rise in infections with Highly Resistant Micro-Organisms (HRMOs) is currently seen. This rise is of relevance, because infections with HRMOs are associated with higher mortality, longer length of stay and higher costs compared with infections with Highly Susceptible Micro-Organisms (HSMOs). Also, cross-contamination with HRMOs can occur when adherence to infection control measures are neglected. Infections with HRMOs are typically harder to treat, where resistance to first line antibiotics urges the use of *rescue*- or second line antibiotics with little hope of new

effective alternatives in the near future. Although colonization with a HRMO in critical care patients is often acquired on the Intensive Care Unit (ICU), a large part of HRMOs found during surveillance in the ICU is imported rather than acquired; also: own study results; submitted for publication; Addendum II). This colonization could have occurred during stay on a general ward, in a nursing facility, or in the community; in the latter situation the contribution of antimicrobial resistance in intensive livestock farming seems to be on the rise.
Besides colonization with HRMOs, suboptimal oral health poses a risk factor for developing post-operative infections. Currently, assessment of oral health is not routinely included in preoperative screening of patients scheduled for cardiothoracic surgery.
Measures to prevent nosocomial infections and spread of HRMOs implemented in daily practice in our ICU include contact isolation of those known to harbour HRMO-colonization, use of a Ventilator-Associated Pneumonia (VAP)-prevention *bundle* including standard oral care three times daily, and use of selective decontamination of the digestive tract (SDD). Additionally, in those cardiosurgery patients who are nasal carriers of Staphylococcus aureus (S.aureus), decolonization of nasal and extranasal sites of S.aureus with mupirocin nasal ointment and chlorhexidine soap is pursued in order to reduce the risk of surgical-site infections with S.aureus.
SDD or selective oropharyngeal decontamination (SOD) is widely implemented on Dutch ICUs. The use of SDD or SOD has shown to significantly reduce mortality at day 28 and is associated with significantly less bacteremias and colonization with HRMOs as compared with standard care. Although currently restricted to the ICU and the hemato-oncology population, employment of SDD perioperatively in elective gastrointestinal surgery patients has shown to reduce anastomotic leakage and postoperative infectious complications. Benefits notwithstanding, SDD does significantly alter the composition of intestinal microbiota; clinical consequences of this effect are currently unknown.
Presently, surveillance screening in order to detect HRMOs will only occur on ICU-admission or in the occasion of outbreaks; only then appropriate measures will be taken to optimize antibiotic therapy and prevent cross-transmission.
In other words: at present, we deploy a reactive, instead of preventive strategy.
Hypothesis:
Recognition of colonization with HSMOs and HRMOs at an earlier stage and subsequent use of better preventive measures such as contact isolation, eradication and antibiotic stewardship may help patient outcomes and may as well be cost-effective. Also, optimization of oral health perioperatively could reduce the risk of nosocomial infections, notably VAP. Finally, evaluation of colonization with pathogenic micro-organisms and of the oral cavity and gut microbiota - the constellation of microbes- in general before, during and after hospitalization can help us to elucidate the effect of hospitalization, including ICU stay, on the patient*s microbiota and the clinical effect of alterations in this microbiota during the clinical course.

Study objective

The objective of this observational pilot is the evaluation of incidence of HSMO- and HRMO-carriage, evaluation of oral and gut microbiota before, during and after hospitalization and evaluation of health status related to an ecological niche of these micro-organisms (oral cavity). The results of this preliminary study should eventually lead to interventional studies resulting in improvement in quality and efficacy of care and to improvement in quality of life for critical care patients.
Our hypothesis generates several study questions:
-What is the incidence of colonization with HSMOs, HRMOs, S.aureus, and yeasts in elective cardiothoracic surgery patients before, during, and after hospitalization, including ICU stay?
-What is the composition of oral and faecal microbiota and how does this composition change during the care process including stay in an ICU and a general ward and all its relevant interventions during this stay, such as SDD?
-What is the status of oral health in this population?
-What is the relationship between HSMO- and HRMO-carriage, oral health and socio-economic status?
-What is the relationship between HSMO- and HRMO-carriage, oral health, oral and faecal microbiota and serious adverse outcomes (SAOs) such as ICU-mortality, occurrence of Post-Operative Wound Infections (POWIs), longer (>= 4 days) length of stay in ICU, and longer (>= 4 days) length of mechanical ventilation?
-What is the relationship between abovementioned SAOs and Quality of Life (QOL)?
-What is the duration of acquired HRMO-carriage?

Study design

Prospective, observational, single center cohort study.

Study burden and risks

Participation in this study will bring the individual participating patient in this pilot study benefit nor harm. The collection of cultures from various body sites and from faeces, the examination of the oral cavity and the completion of a questionnaire regarding general health, demographics and life style are all considered a minor burden.
No risk is anticipated as in this observational study no intervention as such is done besides mentioned taking of cultures, assessment of oral health and completion of a questionnaire.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9700 RB
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9700 RB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Adult patients; >= 18 years of age
Elective cardiothoracic surgery
Screening pre-operatively by anaesthesiologist in policlinic in our center
Admitted to ICU post-operatively
- Able to give informed consent by themselves

Exclusion criteria

Minor; < 18 years of age
Unable to give informed consent
For periodontal cultures: patients who are edentate; in edentate patients, a culture of the

plaque of the tongue will be obtained

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-04-2015
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	05-09-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	24-06-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
CCMO	NL49237.042.14