Reconstituting the microbiome after pneumonia

No registrations found.

Ethical review	Positive opinion
Status	Suspended
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21647

Source
NTR

Brief title
RECAP

Health condition

Community-acquired pneumonia

Sponsors and support

Primary sponsor: Winclove
Source(s) of monetary or material Support: TKI grant

Intervention

Outcome measures

Primary outcome

1. The difference in microbiota reconstitution over different timepoints after hospitalization for CAP.

Secondary outcome

1. Incidence of adverse events.
2. Difference in mean cytokine response levels between groups.
3. Incidence and duration of antibiotic-associated diarrhoea, based on Bristol-stool scale scores.
4. To link cytokine response levels to microbiome composition and clinical endpoints

Study description

Background summary

Community-acquired pneumonia (CAP) is the most important infection in terms of numbers of patients for which antibiotics are given in the hospital. It is known that after a severe pneumonia and subsequent antibiotic treatment, the gut microbiome is severely perturbed. An association has been described between the extent of this dysbiosis and readmission rates for pneumonia and sepsis.
In recent years we deepened our understanding of the role that the intestinal microbiome plays in the local and systemic immune system. Reconstitution of the severely perturbed microbiome after antibiotic treatment in patients with pneumonia could improve the immune status of patients and thereby ultimately lower readmission and infection rates.
In this pilot study we investigate whether a 90-day treatment with a selected probiotics mixture can reconstitute the gut microbiome diversity after antibiotic treatment for CAP.

Study objective

90-day treatment with a selected probiotics mixture can reconstitute the microbiome diversity after antibiotic treatment for community-acquired pneumonia.

Study design

Within 24 hours after hospital admission for CAP, 2-4 days into the hospital admission, 90 days after hospital discharge.

Intervention

90-day treatment with a selected probiotics mixture or placebo after hospital admission for community-acquired pneumonia.

Contacts

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Eligibility criteria

Inclusion criteria

• Age ≥ 18 y
• Clinical suspicion of a new episode of acute lower respiratory tract infection for which treatment with antibiotics is deemed necessary.
• Primary reason for presentation is clinical suspicion of a new episode of acute lower respiratory infection.
• The presence of a new infiltrate on chest radiography or computed tomography (CT).
• Presence of two or more diagnostic clinical criteria
o Cough
o Production of purulent sputum or a change in the type of sputum
o Temperature >38°C or <36.1°C
o Auscultatory findings consistent with pneumonia, including rales, evidence of pulmonary consolidation (dullness on
o percussion, bronchial breath sounds, or egophony), or both
o Leukocytosis (>10×109 white cells per liter or >15% bands)
o C-reactive protein level more than 3 times the upper limit of the normal range
o Dyspnoea, tachypnea, or hypoxemia

Exclusion criteria

• No informed consent is provided by patient or its legal representative.
• Admission to Intensive Care facilities in the current hospital episode.
• Presence of Enterobacteriaceae or Staphylococcus aureus bacteraemia.
• Suspicion/diagnosis of aspiration pneumonia.
• More than 7 days use of probiotics or antibiotics within the last 2 months.
• Patients diagnosed with chronic bowel disease and/or colostomy.
• Pregnancy.
• Parenteral or enteral tube feeding.

• Patient is enrolled in an interventional clinical study of an anti-infective or immunomodulatory therapy.
• Patients who are readmitted to the hospital during the 90-day intervention period will terminate the intervention.
• Patients who are prescribed new antibiotic treatment by the general practitioner during the 90 day intervention period will terminate the intervention.
• Patients who are immunocompromised due to active chemotherapy, uncontrolled HIV infection, stem-cell transplantation, haematological malignancies or high-dose immunosuppressive drugs.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	16-09-2019
Enrollment:	80
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Ethics review

Positive opinion

Date:	13-09-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 49196
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8025
CCMO	NL67870.018.18
OMON	NL-OMON49196

Study results

Summary results
NA