Reconstituting the microbiome after pneumonia

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

Ethische beoordeling	Positief advies
Status	Werving tijdelijk gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21647

Bron
NTR

Verkorte titel
RECAP

Aandoening

Community-acquired pneumonia

Ondersteuning

Primaire sponsor: Winclove
Overige ondersteuning: TKI grant

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	16-09-2019
Aantal proefpersonen:	80
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Ethische beoordeling

Positief advies

Datum:	13-09-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 49196
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
NA