*Effects of Butyrate on Intestinal permeability & inflammation, Intellectual performance, Immune activation and systemic Inflammation in renal disease.

Published: 14-09-2016
Last updated: 14-04-2024

Investigate whether restoration of intestinal butyratelevels improves the intestinal barrier function and decreases the inflammatory status in CKD patients.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Renal disorders (excl nephropathies)
Study type	Interventional

Summary

ID

NL-OMON43237

Source
ToetsingOnline

Brief title
B4I-study

Condition

- Renal disorders (excl nephropathies)

Synonym
chronic kidney disease, Renal failure

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Astellas Pharma,diverse rest fondsen

Intervention

Keyword: Butyrate, Intestinal permeability, Kidney disease, Systemic inflammation

Outcome measures

Primary outcome

The main study parameters consist of markers of:

- Intestinal permeability: quantitative amount of bacterial DNA in blood,

d-lactate, IFAP, indoxyl sulfate

- Inflammation: CPR, IL-6, macrophage and monocyte activation.

Secondary outcome

Other parameters include:

- Serum and faecal butyrate levels

- Lipid spectrum

- Changes in gut microbiome

- Eating habits evaluated by diet lists

- Questionairs evaluating meantal performance and quality of life (RAND-36,

HADS) and fatigue (Checklist Individuele Spankracht)

Study description

Background summary

Among patients with chronic kidney disease (CKD) and renal failure the morbidity and mortality rate is, despite renal replacement therapy, still very high. An important factor is the ongoing chronic systemic inflammation in these patients which is associated with a variety of conditions such as cardiovascular complications, fatigue and depression.
The exact aetiology behind this chronic systemic inflammation is not yet clarified and in the recent years the observed intestinal alterations in CKD have been pointed out as a possible source. An increased intestinal

permeability due to a decreased barrier function is causing bacterial translocation into the blood stream [3], which could be one of the triggers of the inflammatory response.

Butyrate is found in food products such as butter, cheese and milk. Furthermore it is produced through saccharoloytic fermentation of carbohydrates that escape digestion and absorption in the small intestine. Butyrate is an important energy source for intestinal epithelial cells and is known to promote cell differentiation and supress colonic inflammation. Restoration of intestinal butyrate levels could possible restore intestinal epithelial cells and thus barrier function, leading to a decrease in bacterial translocation and a decreased inflammatory response. A decrease in systemic inflammatory response could potentially lead to a decreased morbidity and mortality in patients with renal disease. First of all considering cardiovascular events but possibly also with regard to complaints such as fatigue and depression.

Study objective

Investigate whether restoration of intestinal butyratelevels improves the intestinal barrier function and decreases the inflammatory status in CKD patients.

Study design

Non-randomized clinical trial.

Intervention

Oral administration of 4 grams sodium butyrate a day for one month.

Study burden and risks

Oral butyrate has been given before to human subjects in identical dosages without adverse effects. In previous trials conducted in the AMC (MEC 13/239 and MEC 2014_291) no side effects were reported. For the dialysis patients blood samples will be collected prior dialysis and will thus not cause an additional risk or burden for the patients. For the post-NTX group the venous puncture will cause a small additional burden.
It is not yet clear whether patients will experience beneficial effects from the treatment.

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

For the haemodialysis group:
- Haemodialysis patients, stable on dialysis for >6 months ;For the post renal transplantation group:
- Functional renal allograft, 6-24 months post transplantation;Furthermore: age 40-70, non-smoking, BMI between 20 and 30.

Exclusion criteria

- Diabetics
- Antibiotic treatment within the last 3 months
- Probiotic use
- Chronic diarrhoea or fulfilling the criteria for irritable bowel syndrome
- Irritable bowel disorder or other comorbidity that might affect the intestinal flora
- Dysphagia
- Active infection (CMV, EBV)

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO

Date:	14-09-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL58389.018.16