The role of the gut microbiome in the pathogenesis of IgA nephropathy

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We want to map the entire bacterial ecosystem in the gastrointestinal tract of patients with IgA nephropathy, in order to gain insight into the processes that may play a role in the development of the disease. This can then lay the foundation for...

Ethical review	Approved WMO
Status	Completed
Health condition type	Nephropathies
Study type	Observational non invasive

Summary

ID

NL-OMON49937

Source
ToetsingOnline

Brief title
The role of the gut microbiome in the pathogenesis of IgA nephropathy

Condition

- Nephropathies

Synonym
glomerulonephritis, IgA nephropathy

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Radboudumc fonds: https://radboudumc.voorradboudfonds.nl/project/iga-nefropathie

Intervention

Keyword: IgA nephropathy, Microbiome

Outcome measures

Primary outcome

Does the gastro-intestinal bacterial ecosystem between patients with IgA nephropathy differ from control renal patients and healthy controls? If so, in what way?

Secondary outcome

1. Can disruption of the gastrointestinal bacterial ecosystem be linked to disease severity?

2. Are there associations between health traits/dietary habits and the gastrointestinal bacterial ecosystem?

Study description

Background summary

IgA nephropathy is a slowly progressing disease that causes kidney damage and leads to kidney failure in about 25-50% of cases. For them, dialysis or renal transplantion is the only solution. The reason why IgA nephropathy develops in some people is unclear and there is no effective treatment yet. The disease is characterized by the precipitation of IgA in the kidneys. IgA is made by immune cells and helps to protect us against infection. The IgA in the blood is normally strongly bound to sugar molecules. In IgA nephropathy patients, something appears to go wrong with the saccharification of the IgA in the blood, causing it to precipitate in the kidneys and eventually leading to kidney damage. An important role in the development of IgA nephropathy appears to be played by immune cells that make IgA in our gastrointestinal mucosa. The IgA they secrete is naturally low in sugars and binds bacteria in the gastrointestinal tract and has a substantial influence on the composition of the bacterial ecosystem in the gastrointestinal tract. An interesting observation in this regard is that the bacterial ecosystem in the saliva and stool of IgA nephropathy patients is different from that of healthy people.

This could indicate a disturbance of the immune system in the gastrointestinal tract of IgA nephropathy patients. Little is known about this at the moment.

Study objective

We want to map the entire bacterial ecosystem in the gastrointestinal tract of patients with IgA nephropathy, in order to gain insight into the processes that may play a role in the development of the disease. This can then lay the foundation for new forms of treatment.

Study design

This is a clinical observational study.

Study burden and risks

This is an observational study in which participants complete a questionnaire, have their blood pressure measured and donate body fluids (urine, sputum, faeces and blood). In our view, there are no risks associated with this. The burden for participation in this study is minimal and consists of a 1-hour visit to our outpatient clinic.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Biopsy-proven
eGFR 15 - 90 ml/min/1.73m2
Age 18 - 70 years

Exclusion criteria

No informed consent
Secondary causes of glomerular IgA depositions:
- Liver disease; cirrhosis, hepatitis B
- Gastro-intestinal disease; inflammatory bowel disease (IBD), celiac disease, major gastro-intestinal surgery
- Skin disease; dermatitis herpetiformis, psoriasis
- Pulmonary disease
- Malignant disease
- Current infection
- IgA monoclonal gammopathy
- The use of immunosuppressive drugs
- Antibiotic treatment < 3 months
- CKD stage 5 / dialysis
- Pregnancy

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial

Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	27-10-2021
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO

Date:	28-09-2021
Application type:	First submission
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
CCMO	NL78440.091.21