The DIMID1-trial: Effect of Donor Intestinal Microbiota Infusion on residual betacell function in patients with recently diagnosed Diabetes mellitus type 1.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29482

Source
NTR

Brief title
DIMID1

Health condition

type 1 diabetes mellitus

Sponsors and support

Primary sponsor: AMC-UvA
Source(s) of monetary or material Support: na

Intervention

Outcome measures

Primary outcome

Preservation of residual betacell insulin secretion capacity/beta cell function as assessed by mixed meal test (MMT) at 0, 6 and 12 months.

Secondary outcome

1. Immunologic parameters: Changes in immunology based on FACS of periferal leukocyte subsets (changes in Tr1/nTreg/Th2/ Th17/NKT/TCRγδ subsets, islet autoimmunity (CD4 and CD8)) in relation to mucosa innate en adaptive immunity (CCR4, CXCR3,CXCL10) as well as plasma markers of autoimmunity (antiGAD/IA2/c-peptide plasma concentrations) at 0, 2, 6, 9 and 12 months;

2. Intestinal microbiota: Changes in small intestinal (at baseline and 6 months) and fecal gut microbiota composition at 0, 2, 6, 9 and 12 months;

3. Glycemic control: Changes in plasma biochemistry (HbA1c),urine (microalbuminuria) and subsequent exogenous insulin dose use at 0, 2, 6, 9 and 12 months;

4. Intestinal epithelial integrity: Changes in small intestinal epithelial genes (ILLUMINA array) at baseline and 6 months.

Study description

Background summary

We propose to test the effect of multiple infusions of one healthy donor (=allogenic) compared to multipele infusion of own feces (=autologous) on residual betacell function, immunologic status (in periferal blood and mucosa) and gut microbiota composition both in small intestinal (biopsies) and fecal samples. Using this protocol we might be able to disentangle potential causality of intestinal bacteria in the pathophysiology of type 1 diabetes mellitus.

Study objective

To investigate whether microbial transplantation from either allogenic (healthy) or autologous (own) donor, administered through a small intestinal tube, has beneficial effects on immune status, betacell function (Cpeptide secretion upon a mixed meal test (MMT) in recently diagnosed type 1 diabetes mellitus. Moreover, we aim to see which small (intestinal biopsies) and large intestinal (fecal samples) microbiota are associated with these clinical changes.

Study design

At baseline, 2, 6, 9 and 12 months.

Intervention

We will compare the effect of multiple allogenic (using feces of thorouhgly screened healthy donor) versus autologous (=using own feces) fecal transplantation on preservation of beta cell insulin secretion capacity and normalisation of immunological tone (Thelper cell subsets in blood) in subjects recently diagnosed with type 1 diabetes mellitus. Fecal transplantation (using fresh morning fecal sample) will be performed by introduction of a duodenal tube (either by gastroduodenoscopy or by Cortrak device assisted electromagnetic positioning) , followed by total bowel-lavage with cetomacrogol and subsequent of infusion of processed fecal sample. beta cell insulin secretion capacity will be tested by mixed meal test and immunological tone (Thelper cell subsets in blood) by FACS analysis.

Contacts

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Eligibility criteria

Inclusion criteria

Newly diagnosed (< 6 weeks) patients with type 1 diabetes (n=34, aged 18-30 years, BMI 18-25 kg/m2, with still residual betacell function (as indicated by plasma C-peptide > 0.2 mmol/l and/or >1.2 ng/mL after MMT), male/females, will be recruited by poster advertisement.

Exclusion criteria

Subjects with diagnosis or symptoms of another autoimmune disease (eg hypo- or hyperthyroidism, coeliakie, rheumatoid arthritis or inflammatory bowel disease like Crohn/Colitis Ulcerosa) are not able to participate. Smoking, (expected) prolonged compromised immunity (due to recent cytotoxic chemotherapy or HIV infection with a CD4 count < 240) as well as antibiotics use in the last 3 months and PPI use is seen as an exclusion criterium.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2013
Enrollment:	34
Type:	Actual

Ethics review

Positive opinion

Date:	12-11-2012
Application type:	First submission

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
NTR-new	NL3542
NTR-old	NTR3697
Other	METC AMC : 201/295
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A