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

Gepubliceerd: 12-11-2012 Laatst bijgewerkt: 18-08-2022

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…

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

Samenvatting

ID

NL-OMON29482

Bron
NTR

Verkorte titel
DIMID1

Aandoening

type 1 diabetes mellitus

Ondersteuning

Primaire sponsor: AMC-UvA
Overige ondersteuning: na

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-01-2013
Aantal proefpersonen:	34
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	12-11-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3542
NTR-old	NTR3697
Ander register	METC AMC : 201/295
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A