Can the use of the PPAR-gamma agonist rosiglitazon reverse the abnormal distribution of fat, as well as disturbances in glucose and lipid metabolism in HIV-associated lipodystrophy syndrome?

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

Samenvatting

ID

NL-OMON25981

Bron
NTR

Verkorte titel
Rosi-trial

Aandoening

HIV+ patients, with lipodystrophy (based on fat distribution disturbances), not using d4T nor a protease inhibitor.

Ondersteuning

Primaire sponsor: Academic medical centre, Dept of endocrinology and metabolism, F5-170, Meibergdreef 9, 1105 AZ Amsterdam, The Netherlands
Overige ondersteuning: Glaxo Smith Kline (medication only)

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Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Insulin sensitivity at the level of glucose production by liver, glucose uptake by muscle+fat and lipolysis. This will be measured by a hyperinsulinaemic clamp using stabile isotopes (d2-glucose and D5-glycerol) and by performing muscle biopsies at baseline and after 4 months;
2. Fat distribution by a DEXA- and a CT-scan at baseline and after 4 months.

Toelichting onderzoek

Achtergrond van het onderzoek

This placebo controlled studie investigates the effects of Rosiglitazon on insulin sensitivity at central and peripheral level and on fat distribution in patients with HIV-lipodystrophy, who are not using d4T nor a protease inhibitor.

Doel van het onderzoek

Rosiglitazone results in an improvement in insulin sensitivity at the level of the liver as well as peripherally. In addition disturbances in fat distribution could improve, especially in this specific group of patients, who do not use d4T nor a protease inhibitor, which are known to cause lipodystrophy.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Patients will receive either Rosiglitazon 8 mg daily (2/3) or placebo (1/3) during 4 months.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Male;

2. age>18 years;

3. documented HIV-1 infection;

4. HIV-RNA<50 copies/ml;

5. clinical evidence of lipodystrophy;

6. >36 weeks no use of a protease inhibitor;

7. > 24 no use of d4T, >12 weeks on a stabile regimen.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Active hepatitis;

2. ALAT/ASAT>2.5x above normal level;

3. total bilirubin 2.5x above normal level;

4. lactate 2.5x above normal level;

5. anemia;

6. use of medication influencing metabolism/ blood clotting.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	03-11-2003
Aantal proefpersonen:	15
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	04-11-2005

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	NL477
NTR-old	NTR518
Ander register	: N/A
ISRCTN	ISRCTN78808170

Resultaten

Samenvatting resultaten
N/A