

Influence of lactate on the brain and lipid metabolism.

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Lactate decreases TG-VLDL synthesis by the liver by decreased production. Since patients with FCH have a higher production, we hypothesize that they will have a significant decrease in their production.

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

Samenvatting

ID

NL-OMON21752

Bron

Nationaal Trial Register

Verkorte titel

lactate

Aandoening

familial combined hyperlipidemia

Ondersteuning

Primaire sponsor: Academic medical center

Overige ondersteuning: Academic medical center

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

TG-VLDL synthesis by the liver measured by stable glycerol isotopes every hour. With the rate of disappearance curve synthesis will be calculated.

Toelichting onderzoek

Achtergrond van het onderzoek

TG-VLDL synthesis by the liver will be studied during lactate vs saline infusion and in some patients MRS will be applied.

Doel van het onderzoek

Lactate decreases TG-VLDL synthesis by the liver by decreased production. Since patients with FCH have a higher production, we hypothesize that they will have a significant decrease in their production.

Onderzoeksopzet

8 hours per intervention. There are two visits with one intervention with two weeks between them.

Onderzoeksproduct en/of interventie

1. One day of venous lactate infusion and one day of saline infusion as a control, in healthy subjects and FCH patients;
2. MRS scan of the brain will be done before the start of the infusion and at the end of the infusion.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Healthy participants inclusion:

1. Male;
2. BMI < 26 kg/m²;
3. Age 18-65 yrs;
4. Normal HbA1c level;
5. Normal renal and liver function (creatinine < 150 umol/L, normal liver enzymes);
6. Not on any medication affecting glucose or lipid metabolism or affecting brain regulation (anti-depressants/anti-convulsants);
7. Alcohol intake less than 2 units per day;
8. No claustrophobia in the view of the MRS;
9. No foreign metal devices in the view of the MRS;
10. No panic disorder.

Inclusion criteria for people with FCH:

1. FCH patients meet the criteria of the nomogram of Veerkamp(37);
2. Inclusion criteria 3-9 are identical to healthy participants;
3. Males, matched with healthy participants for age;
4. BMI<27 kg/m²;
5. Triglyceride levels >2.5 mmol/l;

6. No relevant active disease;
7. No known cardiovascular disease;
8. No statins intake for at least 6 weeks.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Medication influencing the brain.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-08-2010
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	07-09-2010
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	NL2414
NTR-old	NTR2522
Ander register	METC : 09/010
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A