Cerebrovascular reserve and white matter disease in patients with chronic anemia

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relationship between CVR, CB, and vascular/inflammatory markers Co-localization of white matter damage and regions of low CVR Global and regional rsponse of CVR to simple trnasfusions, exchange transfusions and hydroxyurea.

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

Samenvatting

ID

NL-OMON27211

Bron
Nationaal Trial Register

Verkorte titel
IMPROVE

Aandoening

Sickle Cell Disease, Thalassemia

Ondersteuning

Primaire sponsor: AMC
Overige ondersteuning: No funding

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

relationship between CVR, CB, and vascular/inflammatory markers
Co-localization of white matter damage and regions of low CVR
Global and regional rsponse of CVR to simple trnasfusions, exchange transfusions and hydroxyurea.

Toelichting onderzoek

Achtergrond van het onderzoek

Low haemoglobin levels raise resting cerebral blood flow (CBF) and leave patients with inadequate cerebrovascular reserve (CVR). As a result , impaired CVR represents the strongest risk factor for white matter injury, volume loss, and stroke. The main goal of this project is to identify CVR predictors including CBF, age, sex and vascular stressors in anaemic and control subject using several MRI techniques. While anaemia is correlated with other cerebrovascular risk factors in the general population (hypertension, kidney disease, chronic inflammation, heart failure), we assume that anaemia, by decreasing CVR, created and increased vulnerability to white matter damage in patients with Sickle Cell Disease (SCD). Through the use of simple and exchange transfusions in selected patients with SCD and thalassemia, we will study the relative importance of haemoglobin S% and total haemoglobin level on regional CVR. We will identify other modifiable risk factors (iron overload, vascular inflammation) that may impair CVR. By comparing CVR and white matter damage across a broad spectrum of SCD and thalassemia syndromes, we will be able to separate the damaging effects of haemolytic anaemias in general froom damage specifi to sickle haemoglobin.

Doel van het onderzoek

relationship between CVR, CB, and vascular/inflammatory markers
Co-localization of white matter damage and regions of low CVR
Global and regional rsponse of CVR to simple trnasfusions, exchange transfusions and hydroxyurea.

Onderzoeksopzet

2 MRIs

Onderzoeksproduct en/of interventie

Blood draw, Neurocognitive tests, infusion placed. ECG leads or pulse unit placed, 15 minutes structural MRI, 15 min Functional MRI pre-ACZ, administration of ACZ, 15 min ASL assesses time course, 15 min functional MRI post ACZ.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patient group:
Sickle cell disease,
Thalassemia major, thalassemia intermedia, and HbH disease
18 years of age or older
Informed consent

Control Group:
Either AS or AA haemogobin
18 years of age or older
Informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patient group:
Hospitalization in the past month for any reason
Inability of the patient to provide informed consent
Contraindications for MRI, such as claustrophobia or the presence of metal in the body
Sickle cell crisis at the moment of participation up to one month prior to participation
History of cerebral pathology that comprimized measeurements, such as cerebral palsy, brain

tumour, meningitis, overt infrarct
Brain surgery performed in the last 3 months

ACZ contraindications
Severe liver, heart of renal dysfunction (clearance <10 mL/min)
Allgergy to sulphonamide
Pregnant or breastfeeding
Use of phenytoin, procaïne or acetylsacylic acid
Risk of hypokalaemia
Addison's disease
Severe asthma or emphysema

Control Group:
Any known chronic illness that may compromise subject safety or data integrity.
Vascular risk factors
Hypercholesterolemia
Contraindications for MRI
Contraindications for ACZ
Developmental delay, stroke, seizure disorder, or neurological conditions other than simple migraine
inability to cooperate with MRI examinations
Diabetes
Uncontrolled hypertension or history of hypertension

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Factorieel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	15-08-2018
Aantal proefpersonen:	140
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	20-03-2019
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	NL7620
Ander register	METC AMC : METC 2018_215

Resultaten