N-Acetylcysteine in Patients With Sickle Cell Disease (NAC).

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Our primary hypothesis is that the drug N-Acetylcysteine, a scavenger of free oxygen radicals and a precursor of glutathione, can reduce the frequency of daily life pain in patients with Sickle Cell Disease by reducing oxidative stress.

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

Samenvatting

ID

NL-OMON28196

Bron
NTR

Verkorte titel
NAC trial

Aandoening

Sickle Cell Disease
Sickle Cell Anemia
Painful Crisis
Pain

Sikkelcel ziekte
Sikkelcel anemie
Pijnlijke crise
Pijn

Ondersteuning

Primaire sponsor: Academic Medical Center, Amsterdam
Overige ondersteuning: - ZonMw
- Academic Medical Center, Amsterdam

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The frequency of SCD related pain in daily life in patients with Sickle Cell Disease evaluated over a period of 6 months.

Toelichting onderzoek

Achtergrond van het onderzoek

The primary aim of this study is to evaluate the effect of the drug N-Acetylcysteine on the frequency of pain in daily life in patients with Sickle Cell Disease (SCD).

Pain is an invalidating hallmark of this disease and has a considerable impact on the Quality of Life of patients and the medical health care system. Oxidative stress is hypothesized to play a central role in its pathophysiology. In pilot studies the administration of N-Acetylcysteine (NAC) resulted in a reduction of oxidative stress. Moreover, administration of NAC seemed to decrease hospitalization for painful crises in a small pilot study in patients with SCD.

This study will be performed as a multicenter, randomized, controlled trial where patients will be treated with either NAC or placebo for a period of 6 months. We expect that NAC can reduce the frequency of pain in patients with SCD, thereby improving their quality of life and participation in society.

Doel van het onderzoek

Our primary hypothesis is that the drug N-Acetylcysteine, a scavenger of free oxygen radicals and a precursor of glutathione, can reduce the frequency of daily life pain in patients with Sickle Cell Disease by reducing oxidative stress.

Onderzoeksopzet

Evaluated over a 6 month intervention period with montly follow-up visits.

Onderzoeksproduct en/of interventie

Experimental:

N-Acetylcysteine (N-Acetylcysteine 600mg 1 oral tablet twice daily during 6 months).

Placebo Comparator:

(Placebo 1 oral tablet twice daily during 6 months).

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age 12 years or older;

2. Sickle cell disease, either homozygous sickle cell disease (HbSS), compound heterozygous

sickle cell disease (HbSC), HbSβ0 or HbSβ+ thalassemia;

3. History of at least 1.0 painful crisis per year in the past 3 years (visit to medical facility is not required).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Chronic blood transfusion or transfusion in the preceding 3 months;

2. Painful crisis in the last 4 weeks (with respect to the moment of inclusion);

3. Pregnancy, breast feeding or the desire to get pregnant in the following 7 months;

4. Known active gastric/duodenal ulcers;

5. Hydroxycarbamide (HC) treatment with change in dose in the last 3 months or started on HC shorter then 6 months prior to study;

6. Known poor compliance in earlier trials regarding the completion of pain diaries;

7. Insufficient compliance in run-in period;

8. Known hypersensitivity to acetylcysteine or one of the other components of the study medication.

Onderzoeksopzet

Opzet

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

Deelname

Nederland
Status: Werving gestart

(Verwachte) startdatum:	01-03-2013
Aantal proefpersonen:	140
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	22-01-2013
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	NL3660
NTR-old	NTR3806
Ander register	EudraCT / CCMO : 2012-004892-37 / NL 41205.018.12;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A