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N-AcetylCysteine in the treatment of Sickle Cell Disease

Submission date	Recruitment status	[X] Prospectively registered
23/08/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
23/08/2007	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
08/09/2008	Haematological Disorders	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
NTR1013

Study information

Scientific Title

Acronym
NAC in SCD

Study objectives
We hypothesise that treatment of sickle cell patients with N-acetylcysteine (NAC) results in reduced red cell phosphatidylserine (PS) exposure, reduced endothelial activation, increased nitric oxide (NO) availability, reduced coagulation activation and reduced inflammation detectable with specific laboratory testing, as well as a reduction of irreversibly sickled cells (ISC's) and Heinz Body formation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Randomised, active controlled, parallel group trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Sickle cell disease

Interventions
N-acetylcysteine 1200 mg or 2400 mg a day.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
N-acetylcysteine

Primary outcome(s)
Primary end-points are the effects of NAC on the laboratory markers (haemoglobin, red blood cell counts, reticulocyte counts, leukocyte counts and differentiation, platelet counts, erythrocyte sedimentation rate, a blood smear will be analysed microscopically for the number of ISC per field, as well as the number of Heinz bodies, intra-erythrocytic reduced glutathione [GSH] and oxidised glutathione [GSSG] levels, NO availability, SRBC phosphatidylserine [PS] exposure, annexin V, creatinine, blood-urea nitrogen [BUN], electrolytes, transaminase levels, albumin levels, lactate dehydrogenase [LDH], indirect bilirubin levels, free haemoglobin levels,

high sensitive C-reactive protein [hsCRP], vascular cell adhesion molecule-1 [sVCAM-1], endothelin [ET-1], interleukin-8 [IL-8], pro-thrombin fragments [F1.2], D-dimer levels, protein S [free and total] and C activity, Von Willebrand factor antigen [vWF-Ag] activity).

Key secondary outcome(s))
Tolerability of study medication (in this phase admittedly in a non-controlled fashion) at every visit by history taking and by scoring of a NAC for SCD check-list.

Completion date
31/12/2008

Eligibility

Key inclusion criteria
1. High performance liquid chromatography confirmed diagnosis of sickle cell anaemia (HbSS), sickle-haemoglobin C disease (HbSC) or sickle cell trait disease (HbSa) genotype
2. Aged 18 to 65 years
3. Written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Not Specified

Key exclusion criteria
1. Blood transfusion in the preceding four months
2. Pregnancy or the desire to get pregnant in the following seven months
3. Concomitant use of hydroxyurea, vitamin K antagonists or other oral anticoagulants, or contraindications for NAC
4. Impaired renal function of more than 60% (as assessed by the Kockroft-Gauld equation)
5. Known gastric or duodenal ulcer
6. Concomitant use of anti-hypertensives, sildefanil or nitrates

Date of first enrolment
01/10/2007

Date of final enrolment
31/12/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Centre (AMC)
Amsterdam
Netherlands
1100 DD

Sponsor information

Organisation
CURAMA Study Group (The Netherlands)

Funder(s)

Funder type
Research organisation

Funder Name
CURAMA Study Group (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration