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

Contact name

Dr B.J. Biemond

Contact details

Academic Medical Centre (AMC)
Department of Clinical Chemistry
P.O. Box 22660
Amsterdam
Netherlands
1100 DD
+31 (0)20 566 7391
b.j.biemond@amc.uva.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

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 measure

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).

Secondary outcome measures

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.

Overall study start date

01/10/2007

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

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

Target number of participants

10

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 recruitmentNetherlands

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

Sponsor information

Organisation

CURAMA Study Group (The Netherlands)

Sponsor details

c/o Dr B.J. Biemond Academic Medical Centre (AMC) Department of Clinical Chemistry P.O. Box 22660 Amsterdam Netherlands 1100 DD

Sponsor type

Research organisation

Funder(s)

Funder type

Research organisation

Funder Name

CURAMA Study Group (The Netherlands)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration