NAC Trial

Reducing the incidence of painful crises in patients with sickle cell disease

REGISTRATION FORM - I

Please complete this form when the ICF is signed, prior to the start of the run-in period.
The separate randomisation form will be completed after the run-in period.

Send forms to the Trial Office Hematology, Department of Haematology F4-224, fax: +31(0)848838087, e-mail: hemat.trial@amc.nl, phone: +31(0)205669111 beeper 59255

Date of Birth

|__|__||__|__||__|__|__|__|

Responsible Physician

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1. Contact Person for questions:

Name: …… Phone and e-mail: ……

2. Site

NL

- O AMC
- O Erasmus MC (EMC)
- O UMC Utrecht (UMCU)

BE

- O Brugmann
- O HUDERF
- O St. Pierre
- O St. Luc
- O Erasme
- O Citadelle (Liège)

UK

- O Guys'& St. Thomas NHS (London)

3. Inclusion criteria		**YES**	No
1.	Sickle cell genotype HbSS, HbSC, HbSβ+ or HbSβ0	O	O
2.	Age **≥12** years	O	O
3.	History of **≥3** painful crises in the past **3** years *****	O	O

4. Exclusion criteria		Yes	**NO**	**n.a.**
1.	Chronic blood transfusion scheme or blood transfusion in the past 2.5 months *(If YES, postpone randomisation until eligible)*	O	O	
2.	Painful crisis in the past 2 weeks ***** *(If YES, postpone randomisation until eligible)*	O	O	
4.	Currently breastfeeding or pregnant, or the desire to get pregnant in the following 7 months	O	O	O
5.	Known, active gastric or duodenal ulcers	O	O	

***** *A **crisis** is defined as a severe, painful, sickle cell related episode of ≥24 hours where a subject experienced significant impediments in daily activities, and pain medication was taken. A visit or admission to a medical facility is **not** obligatory.*

Date: ____ / ____ / _____

Investigator's signature: .....

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Responsible Physician

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4. Exclusion criteria		Yes	**NO**	**n.a.**
6.	Hydroxycarbamide (Hydrea) treatment with change in dose in the last 2.5 months or started shorter then 5.5 months ago. *(If YES, postpone randomisation until eligible)*	O	O	X
7.	Known hypersensitivity to N-Acetylcysteine or one of the other components of the study medication *(Lactose, microcrystalline cellulose)*	O	O	X
8.	Use of pain medication for sickle-cell related pains on more than 15 days per month in the past 6 months *(Chronic pain)*	O	O	X

INFORMATION GIVEN BY THE TRIAL OFFICE

Registration number …….. NAC |__|__|__|
(this is <u>not</u> the randomisation number or the patient study ID)

Date of registration (dd/mm/yy) ..... |__|__||__|__||__|__|

Approved by Trial Office (Signature): ……..

Date: ____ / ____ / _____ Investigator's signature: .....