# A randomised double blind controlled trial of oral ephedrine/etilefrine in the prevention of recurrent (stuttering) attacks of priapism in sickle cell disease: a multicentre international study in older children and adults

Submission date	<b>Recruitment status</b> No longer recruiting	Prospectively registered		
27/10/2005		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
02/02/2006	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
25/01/2011	Haematological Disorders			

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

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# Additional identifiers

# Protocol serial number

09/04

# Study information

## Scientific Title

## Acronym

**PISCES** 

## **Study objectives**

Stuttering attacks of priapism is a harbinger of a major acute attack with its poor sequelae. Penile detumesence depends on alpha adrenergic stimulation such as etilefrine, ephedrine anecdotally. We therefore want:

- 1. To assess if oral ephedrine or etilefrine taken by patients with sickle cell disease is tolerable and if it reduces the rates of stuttering priapism, and or major acute attacks of priapism
- 2. To see if oral ephedrine is comparable to etilefrine in efficacy
- 3. If it is so, to establish the minimum effective dose of ephedrine

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Ethics approval received from the West Midland Multicentre Research Ethics Committee.

## Study design

Double-blind, placebo-controlled trial

# Primary study design

Interventional

# Study type(s)

Treatment

# Health condition(s) or problem(s) studied

Sickle cell disease

#### **Interventions**

Oral ephedrine and oral etilefrine versus placebo

## Intervention Type

Drug

#### Phase

**Not Specified** 

## Drug/device/biological/vaccine name(s)

Etilefrine, Ephedrine

#### Primary outcome(s)

- 1. A change in the frequency of attacks of stuttering priapism from baseline data
- 2. A change in the incidence of an acute (major) attacks of priapism

## Key secondary outcome(s))

Tolerability of oral etilefrine (50 mg) or ephedrine at 15 mg or 30 mg with respect to side effect profile.

## Completion date

01/10/2007

# Eligibility

## Key inclusion criteria

- 1. Male patients with a documented history of sickle cell disease (SCD) irrespective of genotype (alpha thalassemia status will not be determined)
- 2. Patients should be 12 years or over
- 3. Patients with a known history of stuttering priapism (a short self limiting episode lasting up to 4 hours which tends to be recurrent) attributable to SCD
- 4. Patients in active attendance at a designated care centre i.e. one visit in the last six months
- 5. Patients on a stable dose of hydroxyurea for over six months before trial entry, provided a baseline event rate (on treatment) is established before randomisation and no dose change occurs during trial period
- 6. Patients who received a one-off or isolated top up transfusion greater than three months before recruitment date can be entered into study

## Participant type(s)

Patient

# Healthy volunteers allowed

No

## Age group

Adult

#### Sex

Male

## Key exclusion criteria

- 1. Patients with sickle cell trait (haemoglobin A greater than haemoglobin S on alkaline gel electrophoresis or high performance liquid chromatography (HPLC) will not be eligible for randomisation
- 2. Patients known to have elevated blood pressure or a history of cardiac disease
- 3. Patients with SCD and a documented history of stroke in the past
- 4. Patients with a history of acquired vessel aneurysm in the past
- 5. Patients known to be on MAOI (monoamine oxidase inhibitor) drugs or other drugs with significant interactions with study drugs
- 6. Patients known to be intolerant of adrenergic drugs
- 7. Patients with hyperthyroidism
- 8. Patients on a long-term blood transfusion programme to prevent or treat the complications of SCD

#### Date of first enrolment

01/10/2005

# Date of final enrolment

01/10/2007

# Locations

## Countries of recruitment

**United Kingdom** 

England

Nigeria

Study participating centre
Department of Haematology
Liverpool
United Kingdom
L9 7AL

# Sponsor information

# Organisation

Aintree University Hospitals NHS Foundation Trust (UK)

## **ROR**

https://ror.org/02h67vt10

# Funder(s)

# Funder type

Charity

## **Funder Name**

British Society of Haematology (UK)

#### **Funder Name**

Aintree University Hospitals NHS Foundation Trust (UK) - small research grant

## Funder Name

North Middlesex University Hospital NHS Trust (UK) - Haematology Research and Development grant

# **Results and Publications**

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

Not provided at time of registration

# **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2010		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes