

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 27/10/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 02/02/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 25/01/2011	Condition category Haematological Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Study website

<http://www.anaemiaweb.org/pisces.htm>

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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 detumescence 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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Patient information can be found at: <http://www.anaemiaweb.org/Documents/Pisces/Adult%20Patient%20information.pdf>

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 measure

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

Secondary outcome measures

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

Overall study start date

01/10/2005

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

Age group

Adult

Sex

Male

Target number of participants

320

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**

England

Nigeria

United Kingdom

Study participating centre

Department of Haematology

Liverpool

United Kingdom

L9 7AL

Sponsor information**Organisation**

Aintree University Hospitals NHS Foundation Trust (UK)

Sponsor details

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Sponsor type

Hospital/treatment centre

Website

<http://www.anaemiaweb.org/pisces.htm>

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**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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2010		Yes	No