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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

Registration date
02/02/2006

Overall study status
Completed

Last Edited
25/01/2011

Condition category
Haematological Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

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
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