Priapism In Sickle Cell Study

PISCES

Newsletter

INTRODUCTION

Priapism is a prolonged painful erection of the male sexual organ (penis) first associated with sickle cell disease in 1934. It is a common but frequently undisclosed problem among male patients with sickle cell disease with 75% of patients having their first episode before the age of 20 yrs (Adeyoju et al 2002). **Figure 1.**
There are 2 types:- **Stuttering priapism** and an **acute** major attack and the former may precede the latter with its devastating consequences.
PISCES is a randomised double blind placebo controlled trial for the prevention of recurrent attacks of stuttering priapism which we hope may prevent a major attack.
The aims of PISCES are:

(1) To assess if Ephedrine, an oral drug with alpha adrenergic activity or oral 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 Ephedrine is comparable to Etilefrine in efficacy.

ELIGIBILITY CRITERIA

- Must be male patients with a documented history of sickle cell disease irrespective of genotype. (α Thalassaemia status will not be determined).
- Patients should be twelve years or over.
- 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.
- Patients in active attendance at a designated care centre i.e one visit in the last 6-12 months.
- Patients on a stable dose of hydroxyurea for over 6 months before trial entry can be included provided a baseline "event rate" (on treatment) is established before randomisation and no dose change occurs during trial period.
- Patients who receive a "one off" or isolated top up transfusion greater than three months before recruitment date can be entered into study.
- **Initial discussions about trial entry will be established when patient is in "steady state" and *not* experiencing an acute event.**

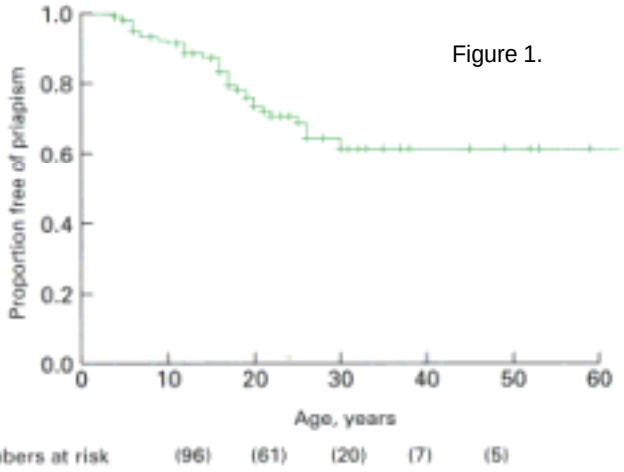


Figure 1.

DIARY OF EVENTS

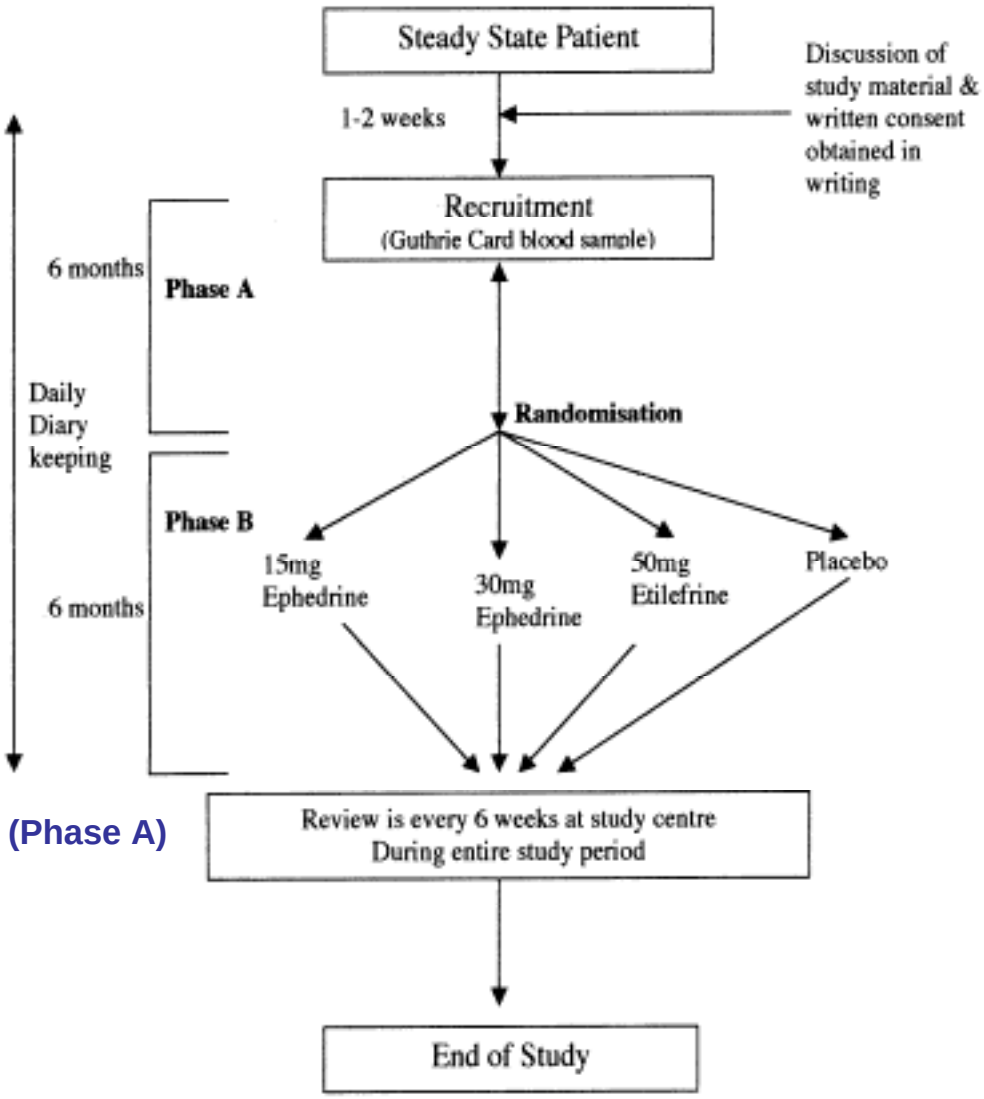
- **MREC application** ***9/12/2004***
- **Ethics granted LUTH** ***19/1/2005***
- **Ethics granted UCH** ***10/3/2005***
- **CTA approval** ***29/3/2005***
- **MREC granted UK** ***30/3/2005***
- **Trial start** ***1/8/2005***

TRIAL STEERING GROUP

Mr Adeyoju FRCS (Urol)	Consultant Urologist
Prof Olu Akinyanju MD FRCP	Professor of Clinical Haematology
Dr Kofie Anie Phd	Clinical Psychologist
Mr Adrian Brooks BSc	Lay Person
Mr Nick George FRCS (Urol)	Consultant Urologist & Group Chairman
Dr Ade Olujohungbe MD MRCP MRCPath	Consultant Haematologist
Dr Anne Yardumian MD FRCP FRCPath	Consultant Haematologist
Verna Angus Davis RGN RM	Counsellor
Mrs Heather Gill BSc MRPS	Community Pharmacist
Julie Morris MSc	Trial Statistician
Prof Y Aken'ova	Professor of Haematology

Endorsed by the Sickle Cell Society of UK & Nigeria, UK Hamoglobinpathy Forum

Patient Flow Chart



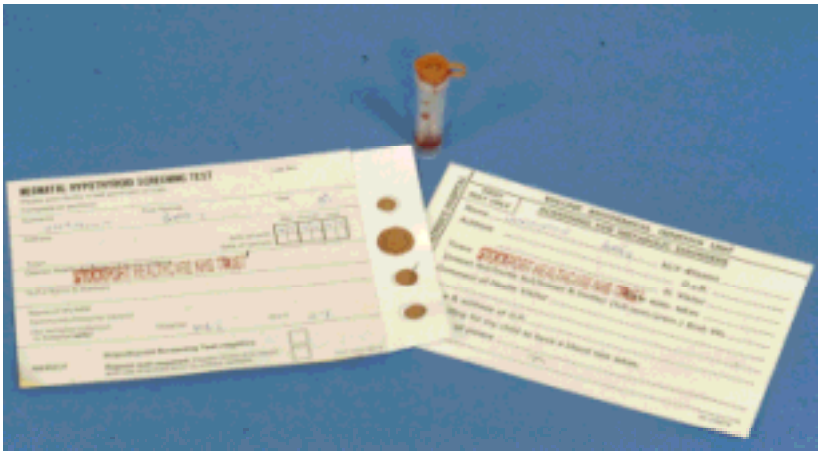
All study drugs are supplied by DHP Pharma
Tel: 01873 812182
Contact: Steve Williams at Stev_williams@dhpclin.com

OBSERVATION ONLY PERIOD (Phase A)

There are a variety of self-help treatments that may help patients during the observation period:
Analgesics
Hydration
Moderate exercise may control attacks. Minimum observation period is 3 months. It is important to establish an **event rate** before randomisation. Please discuss with clinician any queries you may have.

SPOT THE DIAGNOSIS

A drop of blood will be blotted onto Guthrie Cards at registration for confirmation of diagnosis.



All samples will be will be analysed retrospectively.
Please send cards to Department of Haematology, University Hospital Aintree, Liverpool, L9 7AL UK

Download PISCES from the web

Although there is no dedicated website for PISCES, all the forms, patient information leaflets and protocol can be downloaded from the following website:

www.anaemiaweb.org/pisces.htm