

A randomised placebo controlled study of Ephedrine/Etilefrine for prevention of recurrent (stuttering) attacks of priapism in sickle cell disease.

PATIENT INFORMATION SHEET FOR 12-16 YR OLDS

Dear Patient

You are being asked to take part in a clinical study to find out the best to treat recurrent attacks of painful short lasting erections (stuttering priapism) of the penis, which can occur in male children and adults with sickle cell disease.

If you agree to take part we will take a single blood test to check your sickle cell type at the beginning. The study has two parts. Part A and part B, which lasts six months each. During part A you will be asked to fill in a daily diary of how you feel, so that we know how often you have the problem we are studying. During part B you will be given one of four drugs:

1. Placebo (Dummy drug) 2. Ephedrine 15mg 3. Ephedrine 30mg 4. Etilefrine 50mg.
You will be asked to take one tablet at night for six months.

The study drugs have similar side effects, which include sweating and a fast heart beat, but these are not common at the doses used. You will be asked to fill in a daily diary of any problems you develop for the whole of the study period.

Once the study is finished your doctor will discuss with you future treatments.

You can refuse to take part in the study at any time and it will not affect your care in your hospital..

Please note that we have given your parents/guardian a more detailed information leaflet, which you are welcome to read as well. Please ask us any questions you might have.

We hope you will agree to take part in this study.