

DEEP – DEferiprone Evaluation in Paediatrics

DEEP-2 Clinical Trial

EudraCT Number: 2012-000353-31

Study title: Multi-centre, randomised, open label, non-inferiority active-controlled trial to evaluate efficacy and safety of deferiprone compared to deferasirox in paediatric patients from 1 month to less than 18 years of age affected by transfusion-dependent haemoglobinopathies.

Version 2.0

Release date: 30/09/2012



Assent Form

**HELLO! WOULD YOU LIKE TO ANSWER SOME QUESTIONS BEFORE WE START?
WE WANT TO BE SURE EVERYTHING IS CLEAR TO YOU.
IT'S EASY: YOU JUST PUT A CROSS NEXT TO YOUR ANSWERS!**

- | | | |
|---|------------------------------|-----------------------------|
| 1) Do you understand what the doctor was explaining and what this trial is for ? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 2) Do you understand that you'll be taking a syrup or some tablets to dissolve in water, so that you will have less iron in your blood? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 3) Do you understand that you'll come to hospital for a blood sample and a check-up on the days your doctor says? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 4) If you ever have any questions or worries, do you know that you can ask the doctors as many questions you like? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 5) If you take the syrup or tablets, do you know that you might feel a bit sick? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 6) If you do feel a bit sick, do you understand that you have to tell your parents and your doctor? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 7) Do you know that if you don't want to carry on, you can change your mind whenever you want and the doctor will simply put you back on your old treatment just like before? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 8) Do you want to take part in this trial? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

Child's Signature

Full name (capital letters)

Doctor's signature

Full name (capital letters)

Date

FOR PRE-SCHOOL-AGE CHILDREN OR THOSE WHO ARE UNABLE TO SIGN

If you want to take part in this trial,
put a cross inside this box.



DECLARATION BY WITNESS

I declare that the child has heard all of the questions in this document as they were read out and has answered yes to each one. The child has had the opportunity to ask questions about the trial and any worries he/she had have been resolved. Lastly, I declare that the child has agreed to take part in the trial. I, the undersigned, do hereby declare that I have no current or potential conflict of interest deriving from my role as a witness in this trial.

Witness's signature

Full name (capital letters)

DECLARATION BY DOCTOR

I have read out the assent form in the presence of the child and he/she has had the opportunity to ask questions about the trial. I also declare that the child has given his/her consent to take part freely and voluntarily and has not been coerced in any way.

Doctor's signature

Full name (capital letters)

Date