

Study Schedule and Planner



For males younger than 18 years with severe haemophilia A or moderately severe to severe haemophilia B with or without inhibitors

THANK YOU FOR JOINING THE BASIS KIDS STUDY.

You/your child's participation is greatly appreciated. Any information learned may help other children and adolescents living with haemophilia in the future.

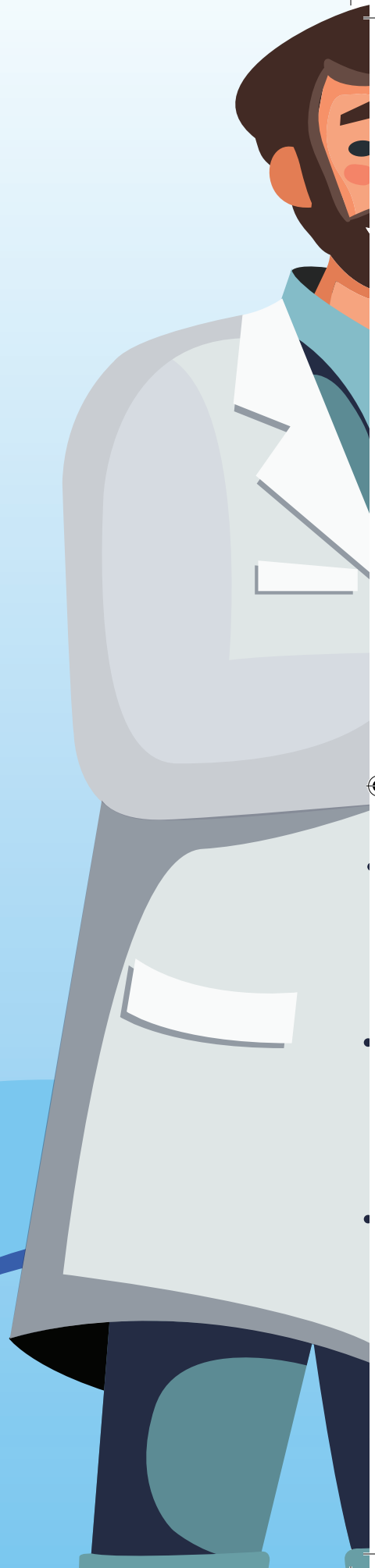
This booklet provides an overview of:

- ✓ The study.
- ✓ How the study treatment is given.
- ✓ What happens at study visits.

It also has space for you to keep track of visit appointments and helpful information and reminders. Attending all study visits can be challenging, but it is important for the doctor to keep an eye on you/your child's health.

The study team will be happy to answer any questions you may have. Remember, participation is voluntary, and you/your child can choose to leave the study at any time.

Thank you,
The BASIS KIDS Study team





What is the BASIS KIDS Study testing?

The BASIS KIDS Study is testing a study medicine given by weekly subcutaneous injection (jab) to see if it can safely prevent bleeds in children and adolescents with either haemophilia A or B.

Who will be participating in the study?

Children and adolescents participating in the study will:



- ✓ Be males younger than 18 years of age.
- ✓ Have severe haemophilia A or moderately severe to severe haemophilia B, with or without inhibitors.
- ✓ Meet additional requirements, as determined by a screening process.

Some people develop 'inhibitors' to replacement factor therapy, which prevent it from working and forming a clot. This makes it more difficult to stop a bleed. The study medicine being tested is not affected by inhibitors.




What happens during the study?

You/your child will be in the study for approximately 14 months. Throughout the study, you/your child will have on-site visits and phone calls with the study team to check on you/your child's health. Some visits may take place at your home if you prefer and if local regulations allow it.



SCREENING

-  Up to 1.5 months
-  1 or more visits

STUDY TREATMENT

-  12 months
-  9 visits
-  5 phone calls

FOLLOW-UP *(after study treatment)*

-  1 month
-  1 phone call

After you/your child completes the study, there may be an option to continue taking the study medicine for a certain period of time as part of a separate study. You can discuss this with the study doctor if you are interested.

SCREENING

Before starting the study, you will need to give permission for you/your child to join by reading and signing an **Informed Consent Form**, which is a document that contains all the details of the study. You/your child may also sign a similar form called the **Assent Form** if you/your child agrees to take part in the study.

The study doctor will then collect information on you/your child's health and medical history and run tests to see if you/your child qualifies for the study.



HEALTH INFORMATION



PERSONAL CHARACTERISTICS



MEDICAL HISTORY



BLEED HISTORY



REVIEW MEDICINES

TESTS AND HEALTH CHECKS



VITAL SIGNS



PHYSICAL EXAMINATION



WEIGHT



HEIGHT



BLOOD TESTS



URINE TEST



HEART ACTIVITY

Will all participants receive the study medicine?

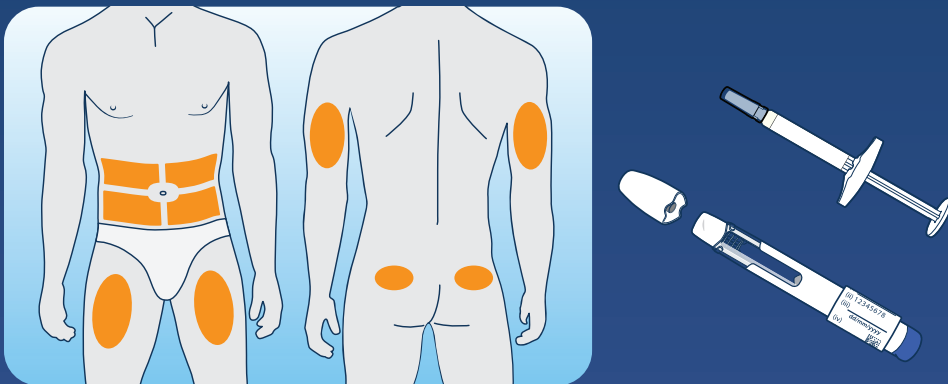
Every child/adolescent who qualifies for the study will receive the study medicine.

Note: You will not use the study medicine to treat bleeding episodes. Use you/your child's usual prescribed haemophilia medication to treat bleeding episodes when they occur, as instructed by the study doctor.

How is the study medicine given?

The study medicine is given as an injection (jab) with a thin needle into the fatty tissue directly below the skin.

Note: Where you/your child receives the injection may depend on whether you/your child use a pre-filled syringe or pen.



You/your child will receive an injection of the study medicine once a week.

The first injection will be given at the study site. You will give the remaining doses of study medicine once weekly. Or, if you prefer, the study site staff can give the doses for you. The study team will provide training on how to give the injection.

See page 16 for how to access helpful resources including the How to Inject the Study Medicine Using the Prefilled Pen and Syringe videos.

What is the Electronic Diary (eDiary)?

You will be given a hand-held electronic device like a smartphone to collect information during the study, including:

Any bleeds you/your child has



- Location on the body where the bleed occurred
- Cause of the bleed (no known cause or the result of an injury)



Any medicines used to treat you/your child's bleeds



Each time you/your child is given a study medicine injection



Make sure you bring the eDiary to study visits and have it with you during phone calls.

The study team will review the information you entered in the eDiary.

STUDY TREATMENT

While taking the study medicine, you/your child will have about 9 in-person visits and 5 phone calls for tests and health checks. If you prefer and if local regulations allow it, 2 of these visits may take place at your home.

You/your child will not have every test at each visit.

In-person visits will consist of:

HEALTH INFORMATION



REVIEW
MEDICINES



REVIEW
eDIARY



REVIEW ON-DEMAND
TREATMENT



STUDY MEDICINE
ADHERENCE CHECK

TESTS AND HEALTH CHECKS



VITAL
SIGNS



PHYSICAL
EXAMINATION



WEIGHT



HEIGHT



JOINT
CHECK



BLOOD
TESTS



URINE
TEST



HEART ACTIVITY
(if needed)



QUESTIONNAIRES



SAFETY
CHECK

STUDY TREATMENT

 **Phone calls will consist of:**

HEALTH INFORMATION



REVIEW
MEDICINES



REVIEW
eDIARY



REVIEW ON-DEMAND
TREATMENT



STUDY MEDICINE
ADHERENCE CHECK

HEALTH INFORMATION



SAFETY
CHECK

You/your child will be continuously monitored throughout the study for any side effects from the study medicine.



STUDY TREATMENT















Use the chart below to keep track of you/your child's scheduled visits and important information.



In-person visit



Phone call

Visit	Day	Scheduled date/time	Notes and reminders
2/3	1		 First dose of the study medicine will be given at the study site. You/your child will have tests before and after receiving the study dose.
4	7		
5	28		 Bring any unused study medicine to you/your child's visit.
6	60 (Month 2)		 Bring any unused study medicine to you/your child's visit.
7	90 (Month 3)		
8	120 (Month 4)		 Bring any unused study medicine to you/your child's visit.
9	150 (Month 5)		
10	180 (Month 6)		 Bring any unused study medicine to you/your child's visit.
11	210 (Month 7)		
12	240 (Month 8)		 Bring any unused study medicine to you/your child's visit.
13	270 (Month 9)		
14	300 (Month 10)		 Bring any unused study medicine to you/your child's visit.
15	330 (Month 11)		
16	360 (Month 12)		 Bring any unused study medicine to you/your child's visit.

FOLLOW-UP *(after study treatment)*

Date: _____

Time: _____

The study doctor will contact you about 30 days after the final dose of study medicine to check on you/your child's health. The study doctor may also ask you/your child to come back for a visit if needed.

 **Phone call will consist of:**



REVIEW
MEDICINES

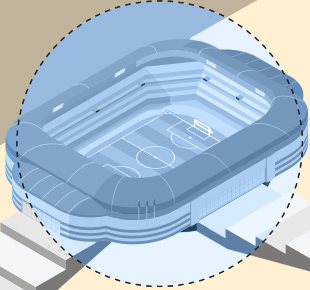


SAFETY
CHECK





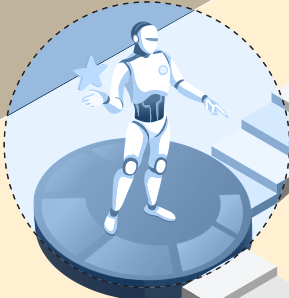
VISIT 7



VISIT 8



VISIT 6



VISIT 3



VISIT 4

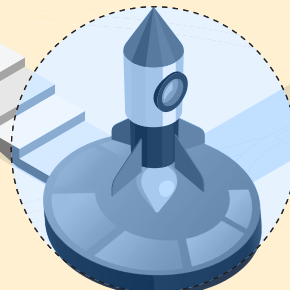
VISIT 5



VISIT 2



VISIT 1



Have fun tracking your visits with the enclosed stickers!



Glossary



Bleed history: The study team will review information on any bleeds you/your child has had in the past year, including how they were treated.



Blood test: Samples of blood will be taken to look at your child's clotting factors and clotting activity. Blood tests will also be used to look at how the study medicine is working, how much study medicine is in you/your child's body, and how the study medicine may be affecting other parts of the body.



Heart activity: A painless test called an electrocardiogram (ECG) will be used to check the electrical activity of you/your child's heart. You/your child will lie down with small sticky patches (electrodes) placed on you/your child's chest, arms and legs. The patches are connected with wires to a computer that picks up the heart's rhythm.



Height: A member of the study team will measure how tall you/your child is without shoes.



Joint check: The study doctor will check you/your child's joints for swelling, movement, strength, pain and flexibility.



Medical history: You will answer questions about you/your child's health, including you/your child's haemophilia, bleeds that needed treatment, any joints affected by bleeds, and any surgeries or medical procedures you/your child may have had.



Personal characteristics: The study team will collect personal information about you/your child, such as you/your child's name and date of birth.



Physical examination: The doctor will check different parts of you/your child's body, such as the heart, lungs, throat, joints and stomach.



Questionnaires: Using an electronic tablet device, you/your child will answer questions about how you/your child feels, you/your child's overall health and how haemophilia affects you/your child's activity and everyday life.



Review eDiary: The study team will go over your eDiary entries at study visits and during phone calls. You will use the eDiary to keep track of any bleeds you/your child has, including the location of the bleed, cause of the bleed and any medicines used to treat it. You will also use the eDiary to keep track of when you give yourself/your child his study medicine injection.



Review medicines: You will answer questions about medicines you/your child is taking now or has taken in the past, including any factor replacement therapy or bypass therapy.



Review on-demand treatment: The study team will review any bleed events you/your child may have had and any medicine that was used to treat you/your child's bleeds.



Safety check: You/your child will be continuously monitored throughout the study for any side effects (unwanted or unintended effects) from the study medicine.



Study medicine adherence check: The study team will go over your eDiary to see when you/your child received his study medicine injections and to make sure they are given correctly.



Urine test: A sample of you/your child's urine will be tested for sugar, protein, and blood. Urine tests can also see how you/your child's kidneys are working.



Vital signs: The study team will measure you/your child's blood pressure (how you/your child's heart is pumping), body temperature and pulse (number of times you/your child's heart beats in 1 minute).



Weight: You/your child will be weighed on a scale without shoes and while wearing light clothing.

For more helpful resources, please scan the QR code below



pin code: bs432



Study contact information

Contact the study team if you have any questions, need to reschedule an appointment, or notice any changes in you/your child's health.

Study doctor:

Phone number:

Email:

Study nurse/study coordinator:

Phone number:

Email:



www.basiskidstrial.com

pin code: bs432

ISSN 979-8-89062-445-1
B7841008_Schedule Planner_EN UK_11_14Feb2023

