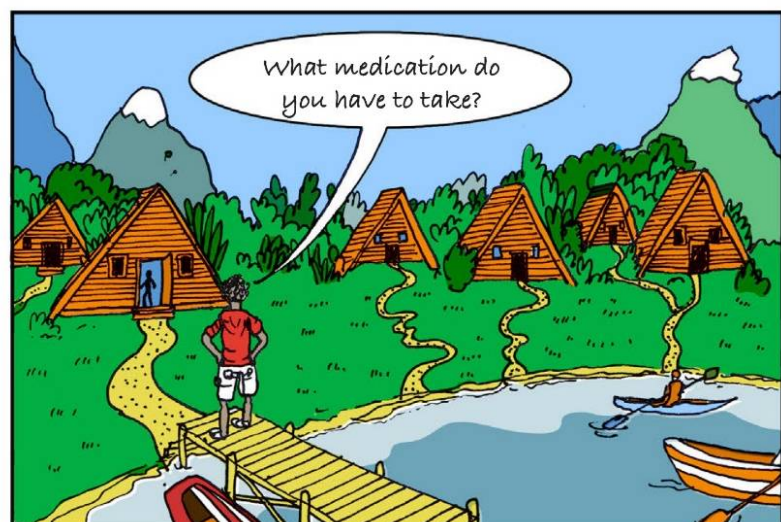
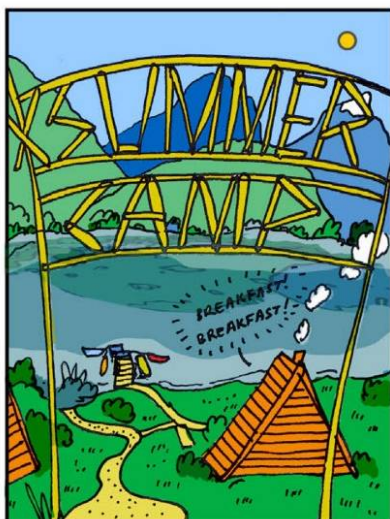
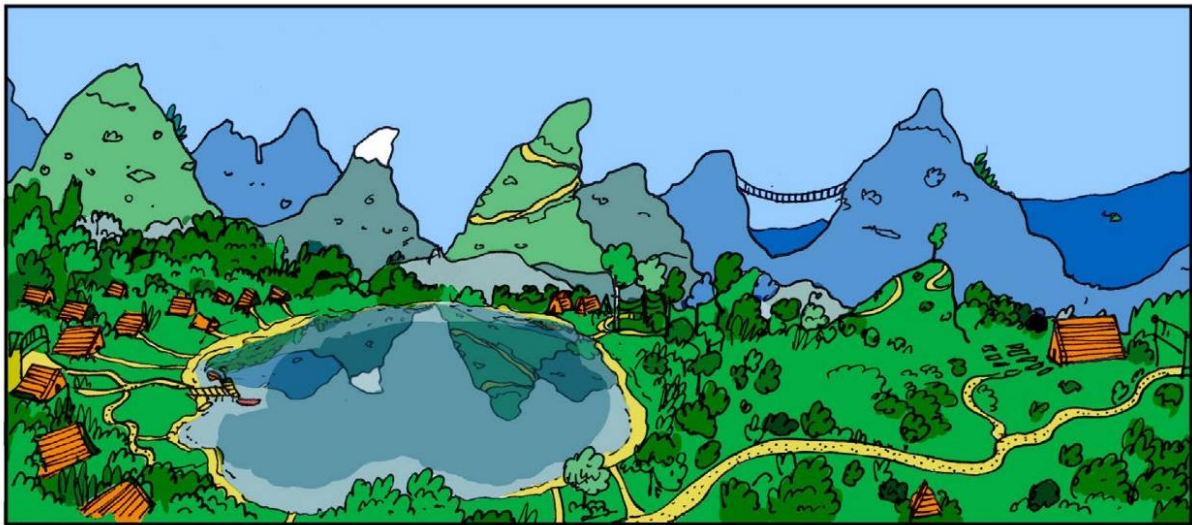


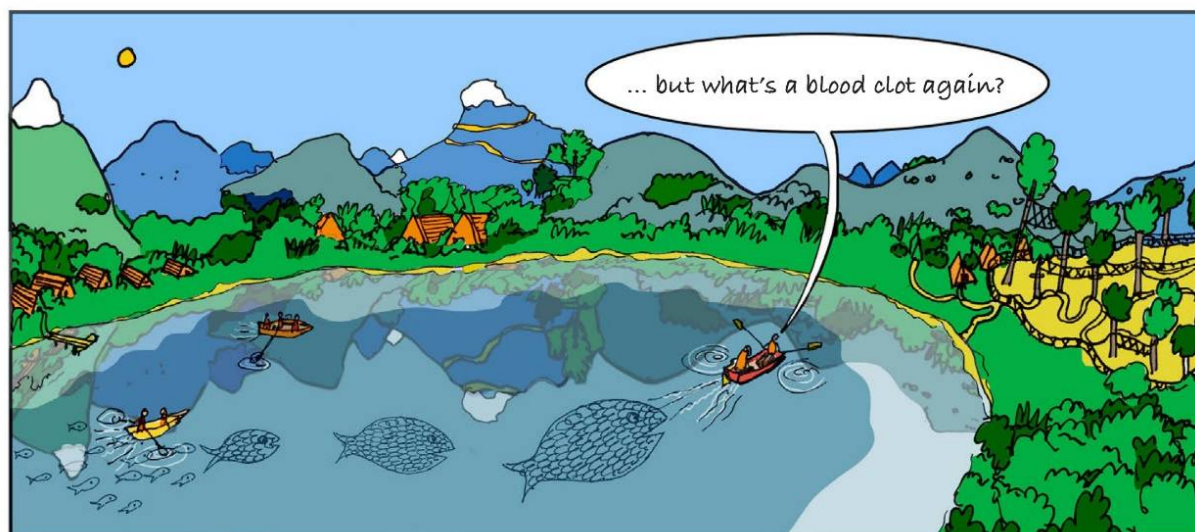
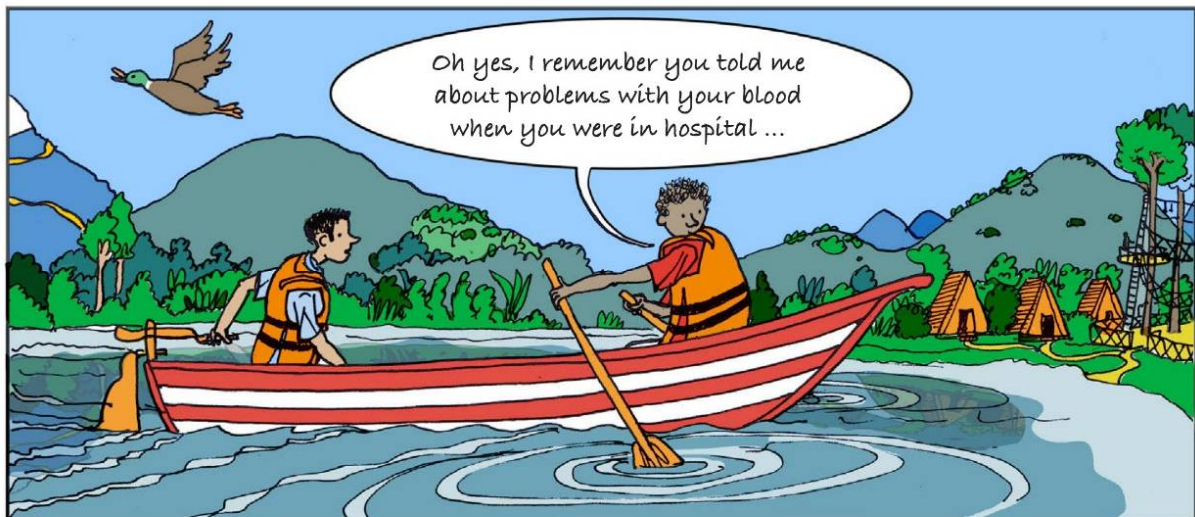
This is a summary of a
clinical study for children.

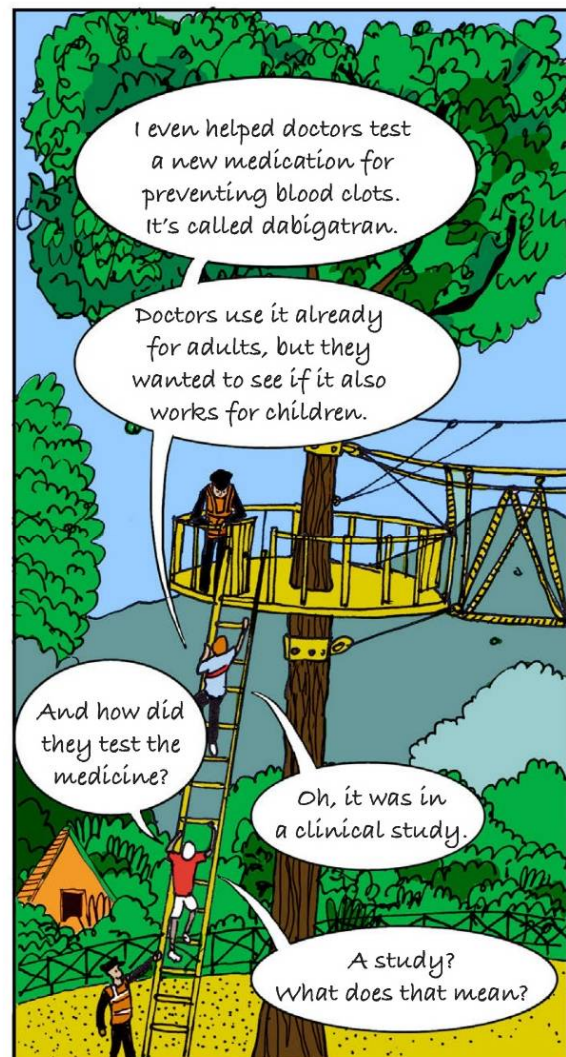
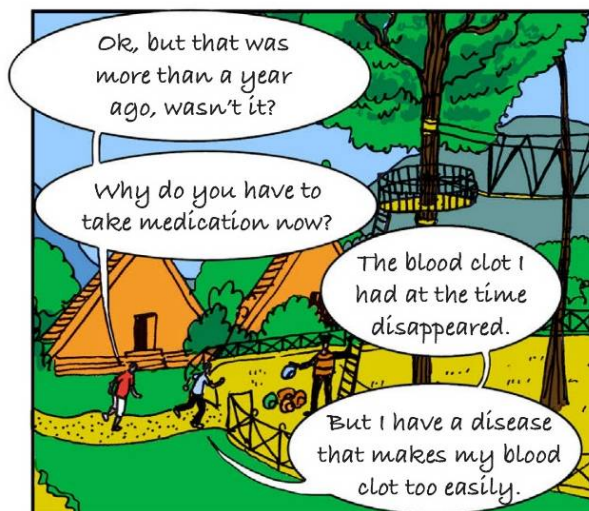
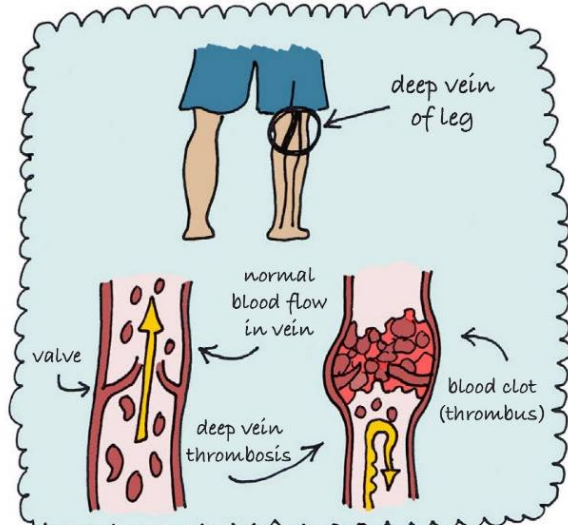
This study tested how safe
dabigatran is in children who
have had a blood clot and are
at risk of developing another
blood clot in the vein.



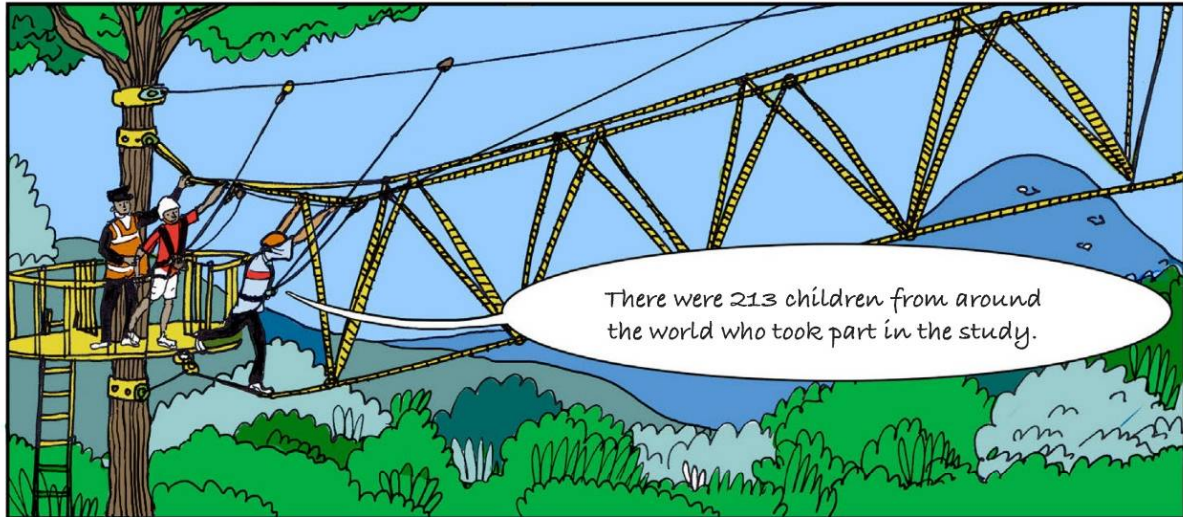
Enjoy reading it!

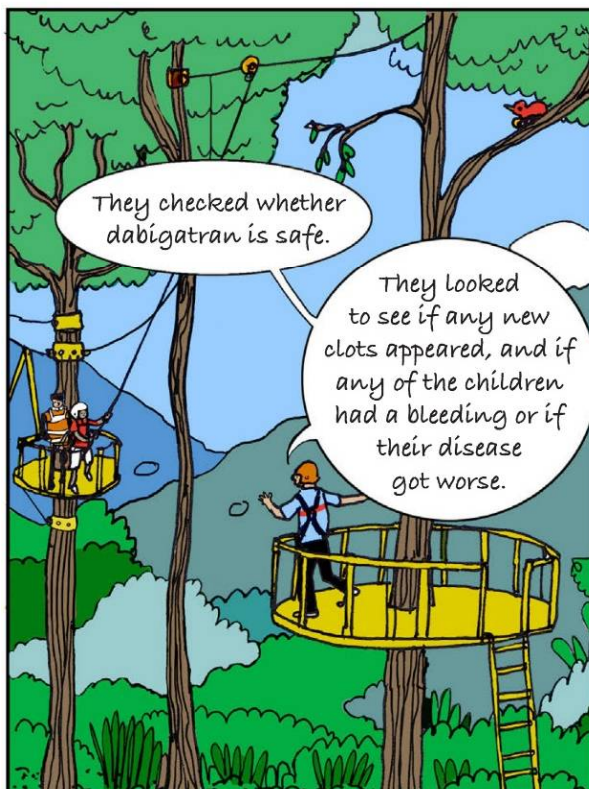
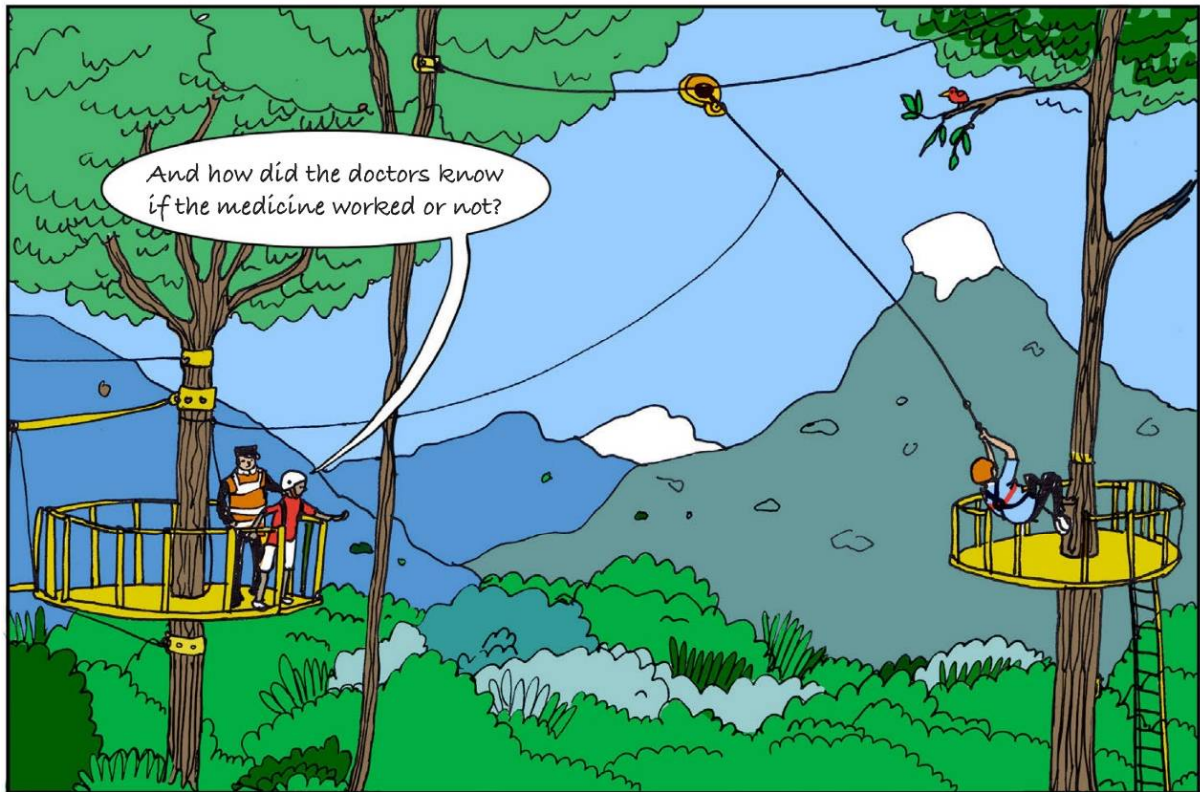




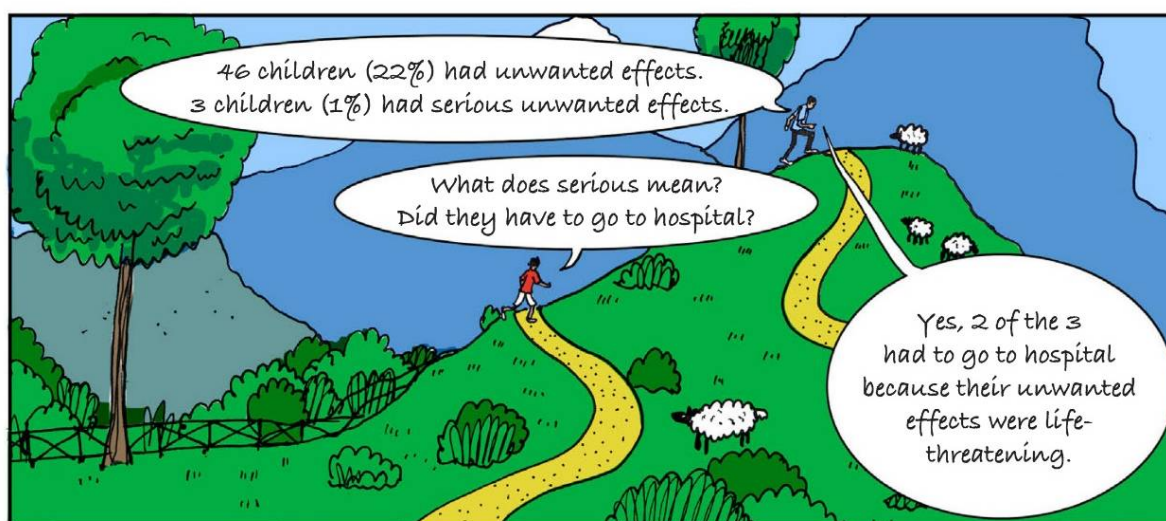
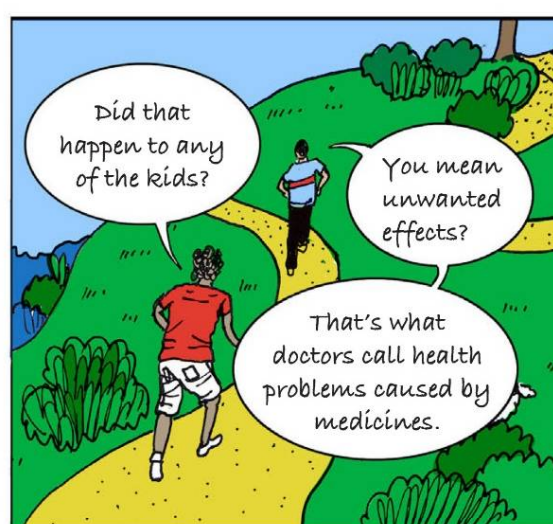
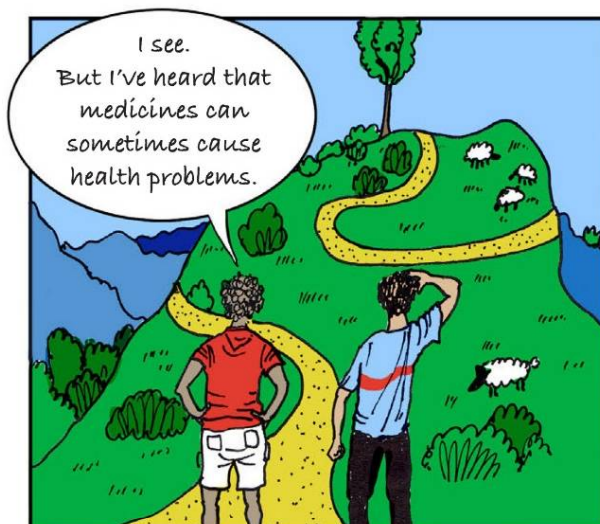
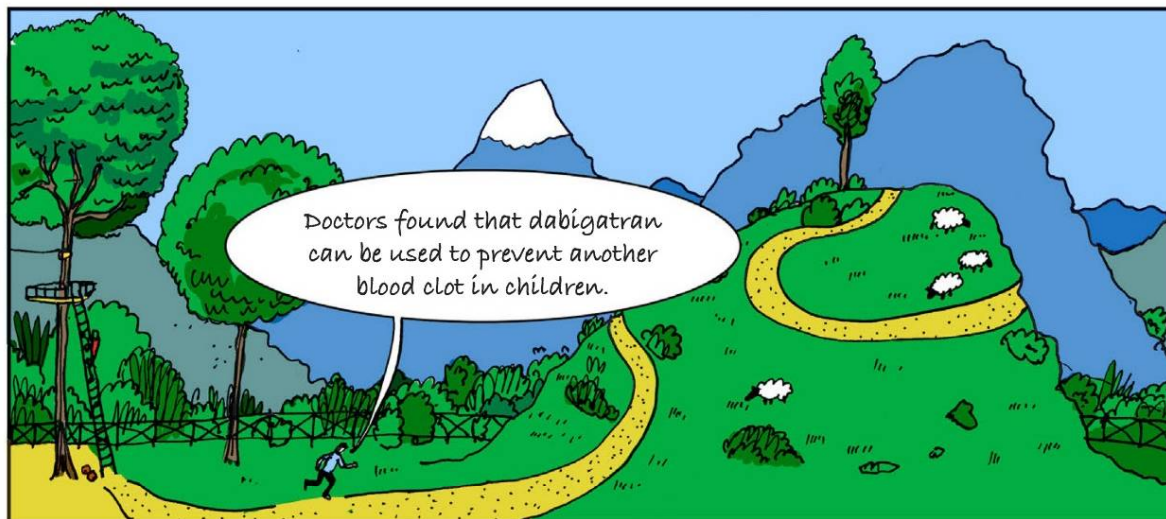


HOW WAS THIS STUDY DONE?





WHAT WERE THE RESULTS OF THE STUDY?



WHERE CAN I FIND MORE INFORMATION?



Illustrations © Studio Badlamb 2020

A study to test how safe dabigatran is in children who have had a blood clot and are at risk of developing another blood clot in the vein

This is a summary of results from one clinical study.

We thank all study participants. You helped us to answer important questions about dabigatran and the treatment of venous thromboembolism (VTE) in children and adolescents.



What was this study about?

The purpose of this study was to find out whether a medicine called dabigatran is safe for children and adolescents with VTE. VTE is a condition in which a blood clot forms in a vein. VTE rarely occurs in children and adolescents. Different things can cause a VTE. It can occur when a young person is not able to move around much, for example, while confined to bed in hospital. A central line, which is a tube inserted into a vein to deliver medicines and draw blood, can also lead to a VTE. In addition, some inherited conditions that affect the clotting of blood can cause a VTE.

Blood clots usually form in deep veins of the leg. There is a risk that a blood clot in the leg can dislodge and travel to the lungs. A blood clot can also form directly in the lungs. This can be very dangerous.

Blood clots require treatment with medicines called blood thinners (anticoagulants). Many of these medicines are given as injections or infusions. Dabigatran is a blood thinner that is taken by mouth. It is already used to treat adults with VTE.



Who took part in this study?

Children and adolescents who previously had VTE (blood clot) and who were at risk of developing another blood clot could take part in this study. Participants could join the study if they had received standard treatment for VTE for at least 3 months. Also, participants who completed Study 1160.106 (a previous study of dabigatran) could join this study.

213 children and adolescents took part in this study. 117 were boys and 96 were girls. The youngest participant was 6 months old and the oldest participant was 18 years old. The average age was 13.

The following table shows the numbers of participants in the study in different regions.

Region ¹	Countries	Number of Participants
Central Europe	Bulgaria, Czech Republic, Hungary, Lithuania, Russia, Turkey, Ukraine, Israel	110
Western Europe	Austria, Belgium, Switzerland, Germany, Denmark, France, Greece, Italy, Norway, Sweden, Finland	49
North America	Canada, United States	44
Latin America	Brazil, Mexico, Argentina	7
Asia	Taiwan, Thailand	3

¹Definition of regions may not match conventional geographical boundaries.



How was this study done?

All participants took dabigatran twice a day. The dose depended on the age and weight of the participant. Dabigatran was taken by mouth as capsules or as pellets mixed with food. Participants received treatment for up to 1 year. The participants and doctors knew what dose the participants were getting.

We wanted to find out whether dabigatran treatment was safe for children and adolescents. To find this out, we studied 3 different health measures. The health measures were:

- Whether participants got new blood clots
- Whether participants had bleeding incidents
- Whether any participants died, especially if they died from a blood clot

Participants visited the doctors regularly. During these visits, the doctors collected information about the participants' health.



What were the results of this study?

We found dabigatran was well tolerated by the children and adolescents in this study. During 1 year of treatment:








- Most of the participants did not get a new blood clot. 3 of 213 participants (1%) got a new blood clot.
- 48 of 213 participants (23%) had one or more bleeding incidents. For 44 out of the 48 participants with bleeding, the bleeding incident was minor.
- No participants died.



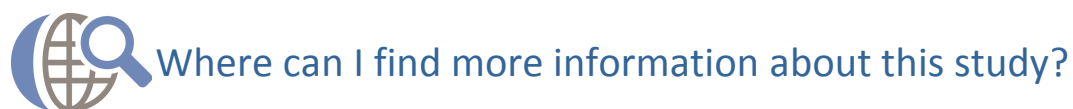
Did participants have any unwanted effects?

Yes, participants had unwanted effects. Unwanted effects are health problems that the doctors think were caused by dabigatran. In this study, 46 out of 213 participants (22%) had unwanted effects.

The table below shows the most common unwanted effects. The table also shows how many participants had each of these unwanted effects.

Type of unwanted effect	Dabigatran 213 participants	
Indigestion (dyspepsia)	11 participants (5%)	
Nosebleed (epistaxis)	7 participants (3%)	
Nausea	7 participants (3%)	
More than usual menstrual bleeding (menorrhagia)	6 participants (3%)	
Stomach pain (upper abdominal pain)	4 participants (2%)	
Bruising (contusion)	4 participants (2%)	

Some unwanted effects were serious because they required a stay in hospital or a longer stay in hospital, or were life-threatening. Unwanted effects were also serious if the doctor thought they were serious for any other reason. In this study, 3 participants (1%) had serious unwanted effects.



You can find further information about this study at these websites:

1. Go to <http://www.trials.boehringer-ingelheim.com/> and search for the study number 1160.108.
2. Go to www.clinicaltrialsregister.eu/ctr-search and search for the EudraCT number 2014-000583-18.
3. Go to www.clinicaltrials.gov and search for the NCT number NCT02197416.

Boehringer Ingelheim sponsored this study.

The full title of the study is: 'Open label, single arm safety prospective cohort study of dabigatran etexilate for secondary prevention of venous thromboembolism in children from 0 to less than 18 years'.

This was a Phase III study. This study started in May 2015 and finished in November 2019.



Are there additional studies?

If we do more clinical studies with dabigatran, you will find them on the websites listed above. To search for these studies, use the words dabigatran and dabigatran etexilate.

Important notice

This lay summary is provided as part of Boehringer Ingelheim's commitment to publicly share clinical study results.

This summary shows only the results from one study and may not represent all of the knowledge about the medicine studied. Other studies may have different results. Usually, more than one study is carried out to find out how well a medicine works and to determine the side effects of a medicine.

This lay summary may include uses, formulations, or treatment regimens for the medicine studied that may be approved or not approved in your country. This lay summary is not intended to promote any product or indication, to guide treatment decisions, or to replace the advice of a healthcare professional.

You should not change your therapy based on the results of this study. Always consult with your treating physician about your therapy.

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