RESPECT ESUS: A study to compare dabigatran and aspirin for preventing further strokes in patients who have had a stroke of unknown origin (1160.189)

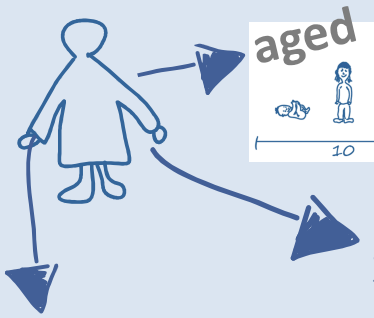
Boehringer Ingelheim

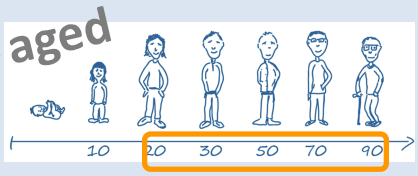
Patients who have had a stroke of unknown origin **have a high chance of having another stroke**.

This **study** wanted to find out:

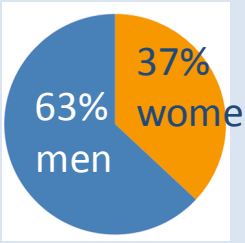
Is **dabigatran** more effective than **aspirin** for prevention of another stroke?

Patients who took part had a stroke of unknown origin before the study





5390 patients from 42 countries took part.
The circles in the map represent the number of patients in the different regions.



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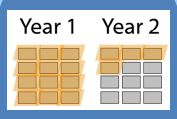
Each patient took

1 110 or 150 mg dabigatran twice daily

or

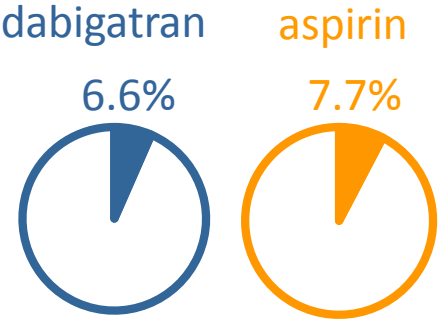
1 100 mg aspirin once daily



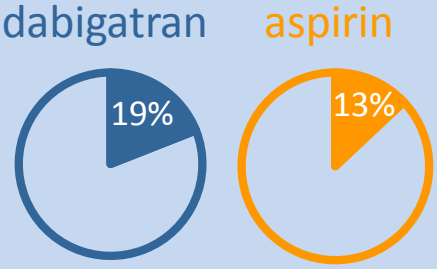
for 1 year & 4 months on average

RESULTS

The results show that the **chances of having a stroke were similar** for both treatments.



19% of patients who took dabigatran and 13% of patients who took aspirin had **unwanted effects**.



World map ©Fotolia by Maeliss

RESPECT ESUS: A study to compare dabigatran and aspirin for preventing further strokes in patients who have had a stroke of unknown origin

This is a summary of a clinical study in patients with a risk of stroke. It describes how researchers did the study and what the results were. We have written this summary for the general public.

We thank all patients who took part in this study. You helped to answer important questions about dabigatran and the treatment of stroke.

What was this study about?

This study included patients who had a type of stroke called 'embolic stroke of undetermined source' (ESUS). Researchers compared 2 different treatments for preventing further strokes. They wanted to find out whether a medicine called dabigatran is more effective than aspirin.

Why was this study needed?

Patients who have had a stroke have an increased risk of another stroke. Some strokes are caused by a blood clot. Patients with this type of stroke take different medicines against blood clotting. The type of medicine that works the best for these patients usually depends on how the blood clot formed in the bloodstream. Some blood clots form around fatty deposits in the vessels.

For some strokes, doctors do not know what causes the blood clot to form. This type of stroke is called ESUS. Patients with ESUS often take aspirin to help prevent further strokes. But doctors do not know what the most effective treatment for ESUS is. This study was done to find out if dabigatran was more effective than aspirin at preventing another stroke.

Which medicines were studied?

Researchers studied the anti-blood-clotting medicine called dabigatran. Dabigatran slows down blood clotting. It reduces the amount of certain proteins needed to form clots. Dabigatran is taken as a capsule by mouth.

Researchers compared dabigatran to another anti-blood-clotting medicine known as aspirin. Aspirin works by preventing small blood cells called platelets from forming clumps that are needed to form clots. Aspirin is taken as a tablet by mouth.

Who took part in this study?

Patients could take part in this study if they had a type of stroke called ESUS within the previous 3 to 6 months.

Overall, 5390 patients took part in the study. 3403 were men and 1987 were women. On average, patients were 64 years old. The youngest patient was 18 years old and the oldest patient was 94 years old. The table below shows the number of patients by geographical region and country.

Geographical Region	Countries	Number of Patients
Western Europe	Austria, Belgium, France, Germany, Greece, Italy, Portugal, Spain, Sweden, Switzerland	2464 patients
Asia	China, Hong Kong, India, Japan, Korea, Malaysia, Singapore, Taiwan, Thailand	1198 patients
Central Europe	Croatia, Czech Republic, Estonia, Hungary, Poland, Russia, Serbia, Slovakia, Slovenia, Turkey, Ukraine	704 patients
North America	Canada, United States	594 patients
Latin America	Argentina, Brazil, Chile, Colombia, Mexico, Peru	225 patients
Other	Australia, Israel, New Zealand, South Africa	205 patients

How was this study done?

The patients were divided into 2 groups. One group of patients received dabigatran and the other group received aspirin. Every patient had an equal chance of being in the dabigatran group or in the aspirin group. Patients were to take the treatment for between 6 months and 3.5 years. The patients did not know which treatment they were taking. The doctors did not know either.

Patients in the dabigatran group took either 220 milligrams (mg) or 300 mg every day. They took dabigatran as 1 capsule twice per day.

Patients in the aspirin group took 1 tablet of 100 mg aspirin once daily.

Patients visited their doctors regularly. During the visits, the doctors collected information on each patient's health.

During the study, researchers compared how many patients had strokes in the dabigatran group and the aspirin group. Researchers also checked whether patients had major bleeding problems during the study. A bleeding problem was major if at least 1 of the following occurred:

- The patient needed a transfusion of blood.
- The bleeding occurred in an important place in the body (such as in the brain).
- The bleeding led to the death of the patient.

What were the results of this study?

The chances of having a stroke during the study were about the same for patients who took dabigatran and for patients who took aspirin. For this analysis, all participants in the study were included. In the dabigatran group, 177 out of 2695 patients (6.6%) had a stroke. In the aspirin group, 207 out of 2695 patients (7.7%) had a stroke. Researchers did statistical tests on the results. They found that it was likely that the difference between the treatment groups came about by chance.

The chances of having a major bleeding problem during the study were also similar for each treatment. For this analysis, all participants who received any study treatment were included. In the dabigatran group, 65 out of 2676 patients (2.4%) had a major bleeding problem. In the aspirin group, 48 out of 2674 patients (1.8%) had a major bleeding problem.

Were there any unwanted effects?

Unwanted effects are any health problems that the doctors thought were caused by the study medicines. In this study, 503 out of 2676 patients (19%) in the dabigatran group had unwanted effects. 344 out of 2674 patients (13%) in the aspirin group had unwanted effects.

The most common unwanted effects seen in at least 25 patients taking either dabigatran or aspirin are shown in the table below.

	Dabigatran 220 mg or 300 mg (2676 patients)	Aspirin 100 mg (2674 patients)
Upset stomach (dyspepsia)	44 patients (2%)	25 patients (less than 1%)
Blood in the urine (haematuria)	39 patients (2%)	12 patients (less than 1%)
Nosebleed (epistaxis)	33 patients (1%)	39 patients (2%)
Stomach pain (abdominal pain upper)	33 patients (1%)	19 patients (less than 1%)

Some unwanted effects were serious because they required a visit to hospital or a longer stay in hospital, were life-threatening or fatal. Unwanted effects were also serious if they led to disability, or a birth defect, or the doctor thought they were serious for any other reason. In this study, 93 patients (4%) in the dabigatran group had serious unwanted effects.
56 patients (2%) in the aspirin group had serious unwanted effects.

Are there additional studies?

If researchers do additional clinical studies with dabigatran, you will find them on the websites listed in the next section. To search for these studies, use the following names: dabigatran or dabigatran etexilate.

Where can I find more information about this study?

You can find the scientific summaries of the study results at these websites:

1. Go to http://www.trials.boehringer-ingelheim.com/ and search for the study number 1160.189.
2. Go to www.clinicaltrialsregister.eu/ctr-search and search for the EudraCT number 2013-003444-24.
3. Go to www.clinicaltrials.gov and search for the NCT number NCT02239120.

Boehringer Ingelheim sponsored this study.

The full title of the study is: 'Randomized, double-blind, Evaluation in secondary Stroke Prevention comparing the EfficaCy and safety of the oral Thrombin inhibitor dabigatran etexilate (110 mg or 150 mg, oral b.i.d.) versus acetylsalicylic acid (100 mg oral q.d.) in patients with Embolic Stroke of Undetermined Source (RESPECT ESUS)'.

This was a Phase 3 study. This study started in December 2014 and finished in August 2018.

Important notice

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

You should not change your therapy based on the results of this study without first talking to your treating physician. Always consult your treating physician about your specific therapy.

Boehringer Ingelheim has provided this lay summary in accordance with European Union transparency obligations.