RE-SPECT CVT: A study to compare dabigatran and warfarin for preventing blood clots in patients who have had a rare type of stroke (1160.248)

Boehringer Ingelheim

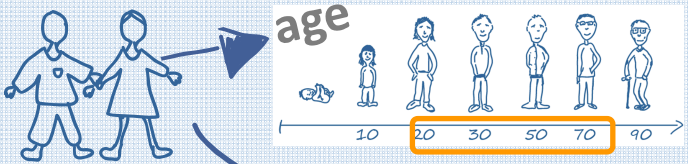
Patients who have had a stroke usually take medicines **against blood clotting**. These can lower the risk of stroke, but can also increase **risk of bleeding.**

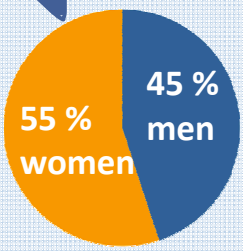
This **study** wanted to find out:

Is a medicine called **dabigatran** as effective and safe as a medicine called warfarin at **preventing blood clots**?

Patients who took part

had a type of stroke called Cerebral Venous Thrombosis (CVT)





120 patients from **9 countries** in Europe and Asia took part.

Each patient took

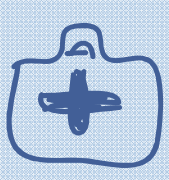
2 150 mg dabigatran

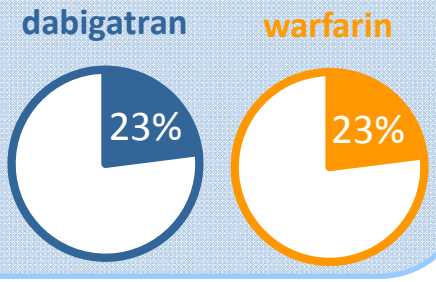
or

X warfarin

(doctors decided individually which dose was needed)

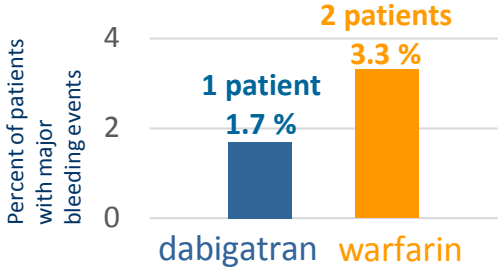
23% of patients who took dabigatran and 23% of patients who took warfarin had **unwanted effects**.





During the study **no patient** in either treatment group had a **blood clotting event**.

1 patient who took dabigatran and 2 patients who took warfarin had a major bleeding event.



RE-SPECT CVT: A study to compare dabigatran and warfarin for preventing blood clots in patients who have had a rare type of stroke

This is a summary of a clinical study about a type of stroke called cerebral venous thrombosis (CVT). This summary describes the results of the study.

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 CVT. Researchers compared 2 different treatments for preventing blood clots/further strokes.

Why was this study needed?

Patients who have had CVT usually take medicines against blood clotting. These medicines can lower the risk of further strokes. But anti-blood-clotting medicines can also increase the risk of bleeding.

The medicine that is most often prescribed for patients who had a CVT is warfarin. This study was needed to find out whether another medicine called dabigatran is as effective and safe as warfarin at preventing blood clots.

Which medicines were studied?

We 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.

We compared dabigatran to a medicine known as warfarin. Warfarin is another anti-blood-clotting medicine that works in a different way to prevent blood clots. Warfarin 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 CVT. They were to have already received a type of anti-blood-clotting treatment right after the CVT event and for 5 to 15 days after.

Overall, 120 patients took part in the study. 54 patients (45%) were men and 66 patients (55%) were women. On average, patients were 45 years old. The youngest patient was 18 years old and the oldest patient was 78 years old. This study was done in 9 countries shown in the table below.

Country	Number of Patients
Portugal	22
Russia	22
India	19
Italy	14
Germany	13
Poland	10
Netherlands	9
France	7
Spain	4

How was this study done?

The patients were divided into 2 groups of equal size. One was the dabigatran group and the other was the warfarin group. Every patient had an equal chance of being in the dabigatran group or in the warfarin group. Patients were to take the treatment for 24 weeks. The patients and doctors knew which treatment the patients were getting.

Patients in the dabigatran group took 2 capsules every day. Each capsule contained 150 mg of dabigatran. Patients in the warfarin group took tablets every day. The doctors determined how many warfarin tablets and the dose each patient needed.

Patients visited the doctors regularly. During these visits, the doctors collected information about the patient's health.

Doctors were to record any blood clots or major bleeding problems that the patients had. We compared how many patients had blood clots or major bleeding problems in the dabigatran group and the warfarin group.

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?

During the study, no patients in either treatment group had a blood clot. The number of patients in either treatment group with major bleeding problems was low. In the dabigatran group, 1 out of 60 patients had a major bleeding problem. In the warfarin group, 2 out of 60 patients had a major bleeding problem. No patients died during this study.

Did patients have any unwanted effects?

Yes, patients in both treatment groups had unwanted effects. Unwanted effects are health problems that the doctors think were caused by the study medicines. In this study, 14 out of 60 patients (23%) in the dabigatran group had unwanted effects. 14 out of 60 patients (23%) in the warfarin group had unwanted effects.

The table below shows the 4 most common unwanted effects.

Unwanted effect	**Dabigatran (60 patients)**	**Warfarin (60 patients)**
Bleeding gums (gingival bleeding)	2 patients (3%)	1 patient (2%)
More than usual menstrual bleeding (menorrhagia)	1 patient (2%)	1 patient (2%)
Headache	0 patients	2 patients (3%)
Bleeding on the brain (subdural haematoma)	0 patients	2 patients (3%)

Some unwanted effects were serious because they required a visit to hospital or because the doctor thought they were serious for any other reason. In this study, 1 patient (2%) in the dabigatran group had serious unwanted effects. 3 patients (5%) in the warfarin group had serious unwanted effects.

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 1160.248.
2. Go to www.clinicaltrialsregister.eu/ctr-search and search for the EudraCT number 2015-004412-38.
3. Go to www.clinicaltrials.gov and search for the NCT number NCT02913326.

Boehringer Ingelheim sponsored this study.

The full title of the study is: 'RE-SPECT CVT: a randomised, open-label, exploratory trial with blinded endpoint adjudication (PROBE), comparing efficacy and safety of oral dabigatran etexilate versus oral warfarin in patients with cerebral venous and dural sinus thrombosis over a 24-week period'.

This was a Phase 3 study. This study started in December 2016 and finished in June 2018.

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 or dabigatran etexilate.

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.