



TICH-2 Lay Results Summary

Background

Bleeding in the brain (intracerebral haemorrhage) is a medical emergency and causes up to 20% of all strokes, and nearly half of all stroke deaths worldwide. Survival rates after a bleed have not changed over several decades, and the only treatment that improves functional outcome is care on a stroke unit and early blood pressure lowering. Around a quarter of bleeds in the brain are complicated by continuation or expansion of the bleeding, which usually occurs within the first few hours after the initial bleed. This is associated with death and increased dependency on others for help.

Tranexamic acid is a drug that has been used to reduce the number of patients who die from bleeding after trauma and after childbirth. Recent research has shown that tranexamic acid needs to be given within 3 hours of the start of bleeding to be effective.

Aims

We undertook an international trial in adults with stroke due to bleeds in the brain, to assess whether tranexamic acid reduced the number of people who were dependent or had died by 90 days after the stroke. We also wanted to measure the effect on early complications (such as amount of bleeding in the brain, and early death) and see if tranexamic acid caused serious side effects such as blood clots or heart attacks. Participants were recruited in hospital within 8 hours of having a stroke caused by bleeding in the brain. If participants were not able to give consent to take part in the study themselves, a relative/friend or hospital doctor gave consent on their behalf in accordance with ethical guidelines.

Half the participants received 1g tranexamic acid injection into a vein followed by an 8 hour 1g drip also into a vein, and the other half received an injection and drip which contained saline (salt water) but no medication (known as a placebo).

A brain scan was performed on admission to hospital and a second research scan was performed 24 hours after treatment to assess whether the bleed had increased in size. Participants were also assessed before they were discharged home and by telephone 90 days after the stroke.

Results

We recruited 2,325 participants (1161 who had tranexamic acid and 1164 who had placebo) from 124 hospitals in 12 countries between 2013 and 2017.

The groups were similar in age, sex, and stroke severity at the beginning of the study.

We found there was no significant difference between the treatment groups in number of people who were dependent or had died 90 days after stroke. However, increase in the size of the bleed occurred less often, fewer people died in the first 7 days after treatment with tranexamic acid, and there were also fewer stroke complications and in those who had tranexamic acid. There was no evidence of tranexamic acid causing any serious side effects such as blood clots or heart attacks.

Patients who had lower blood pressure, and those without a very large amount of bleeding seemed most likely to benefit from the drug.

Conclusion

There was no significant difference in our main outcome, the number of people who were dependent or had died 90 days after stroke. However, there was a reduction in early deaths, and the amount of bleeding in the brain as well as fewer complications in people who had tranexamic acid. Tranexamic is not expensive, it is easy to administer and appears to be safe. Therefore, even if the effect of the treatment is small it could make a difference in the worldwide treatment of stroke patients who have had a bleed in the brain.

Larger trials are likely to be needed to confirm if tranexamic acid can improve the number of people who are alive and independent after stroke due to bleeding in the brain. Focus needs to be given to treating patients earlier (ideally within 3 hours) after stroke onset.