

TITRe2

Summary of the main results of the TITRe2 research study

This leaflet contains a summary of the results of the TITRe2 research study. It has been written for patients who took part in the study.

TITRe2 enrolled over 3,500 patients having heart surgery from 17 hospitals across the UK. The study was carried out between July 2009 and October 2014.

Aims of TITRe2

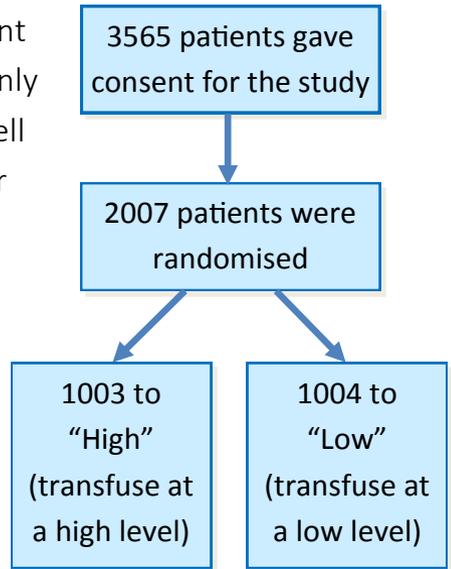
Before the study started there was no clear evidence about when patients should have blood transfusions after heart surgery. At that time, about 4 of every 10 patients were given a blood transfusion but this number varied a lot across the UK. Usually, a haemoglobin measurement (a simple blood test) is used as a guide, but different hospitals and different surgeons were giving blood transfusions at different haemoglobin levels.

This variation showed that doctors were uncertain about when to give a blood transfusion. To resolve this uncertainty, the study aimed to compare the proportion of patients having complications after surgery when given blood at a low haemoglobin level with the proportion having complications when given blood at a high haemoglobin level.

Design of TITRe2

Over 3,500 patients gave their consent to take part in the study. However, only patients whose haemoglobin levels fell below 9g/dL at some point after their surgery became eligible for the main study. This meant that:

- ★ Around 1500 patients (or 40%) who consented did not take part in the main study
- ★ 2007 patients were entered into the main study. These patients were put, by chance, into one of two groups:



“High” haemoglobin strategy:

A blood transfusion was given whenever a patient’s haemoglobin level was below 9g/dL

“Low” haemoglobin strategy:

A blood transfusion was given whenever a patient’s haemoglobin level was below 7.5g/dL

At ALL times a doctor could still give a blood transfusion, or not give one, if he/she thought one was definitely needed/ not needed.

To compare the two transfusion strategies, we counted the number of patients in each group who had a serious complication after surgery. The following complications were included: infections, heart attacks, strokes, kidney problems and serious gut problems.

TITRe2 results

Almost all of the patients in the “high” group had a blood transfusion (92%), whereas just over half of the patients in the “low” group had a blood transfusion (53%).

Slightly more patients had a serious complication in the “low” group (35%) than the “high” group (33%). This difference is very small. It seemed to be due mainly to kidney problems.

In addition, slightly more patients died in the “low” group (42, 4.2%) than the “high” group (26, 2.6%). These rates are very low, and in line with the expected death rates after heart surgery. However, the difference between groups is worrying.

There were no substantial differences between the “high” and “low” groups with respect to other information that we measured to assess recovery. This information included:

- The length of time spent in hospital after surgery.
- Health related quality of life at 6 weeks and 3 months after the operation.
- Lung complications (originally thought to be more common after blood transfusions).
- Other complications.

Impact of TITRe2

- ★ More patients took part in TITRe2 than any other heart surgery study in the UK.
- ★ The results do not support the view that transfusing at a lower haemoglobin level is better.
- ★ We do not know why there were more deaths, but not substantially more serious complications, in the group that were given transfusions at a low haemoglobin level.
- ★ We cannot recommend one strategy as clearly better on the basis of the trial. However, the result does show that transfusion is safe in patients having heart surgery.

For further information

- ★ Contact the **Bristol TITRe2 Research Team**: TITRe2, Clinical Trials and Evaluation Unit (CTEU), Level 7, Queen's Building, Bristol Royal Infirmary, Bristol. BS2 8HW. Tel: 0117 342 3564 or 0117 342 3398. Email: titre2-trial@bristol.ac.uk
- ★ You can obtain **general advice on heart disease** and its treatment from the British Heart Foundation (www.bhf.org.uk, Tel: 08450 708070).
- ★ You can obtain **general information on clinical research** from the UK Clinical Research Collaboration (UKCRC) who produce a booklet called "Understanding Clinical Trials". (www.ukcrc.org/publications/informationbooklets.aspx, Tel: 020 7670 5452).

And finally...

THANK YOU for taking part in TITRe2.
Without you the study would not have been possible.