



Results of the STAMPEDE trial abiraterone comparison

Thank you

Thank you for taking part in the STAMPEDE trial. You are helping us to answer important questions about how to treat people with prostate cancer. This will help other patients with prostate cancer in the future.

This document describes some of the results of the study, from the abiraterone comparison. If you have any questions about it, or about previous results, please speak to your doctor or research nurse.

We wrote this summary in June 2017. We will have more results from this trial in a few years. This summary only includes results from the STAMPEDE trial. Other studies may find different results.

What was the STAMPEDE trial abiraterone comparison about?

The STAMPEDE trial is testing how best to treat prostate cancer. It is testing several new approaches. We already have results from five of these, using the drugs zoledronic acid, docetaxel and celecoxib. The results we will tell you about in this document are the newest results. They are about adding the drug abiraterone to standard hormone therapy. We aimed to see if adding abiraterone could improve how long men lived, and delay the disease getting worse.

Why was the STAMPEDE trial needed?

Prostate cancer is the most common cancer in men in the UK. Almost 47,000 men are diagnosed with prostate cancer in the UK each year. High risk or advanced disease is usually treated with long-term hormone

therapy to stop the disease from growing. But sometimes standard hormone therapy stops working, and the disease gets worse. The STAMPEDE trial was set up to see if we could improve prostate cancer treatment by adding things to standard hormone therapy.

Abiraterone (also known as Zytiga) is a newer type of hormone therapy that works in a different way to standard hormone therapy for prostate cancer. It is currently used to treat prostate cancer in patients whose standard hormone therapy has stopped working. In STAMPEDE we looked at using it earlier, while standard hormone therapy is still working, to see if this improves how men do. We hoped that combining the two types of hormone therapy would improve how long people lived.

Who took part in the abiraterone comparison in STAMPEDE?

People taking part in the abiraterone comparison in STAMPEDE:

- had high risk prostate cancer, or prostate cancer that has already spread to the nodes or other parts of the body;
- were starting long-term hormone therapy for the first time;
- were fit enough to have chemotherapy.

The trial is taking place in more than 100 hospitals throughout the UK, and in five hospitals in Switzerland.

The average age of men joining the abiraterone comparison was 67. Around half had disease that had already spread to other parts of their body. The average PSA before starting hormone therapy was 53ng/mL.

How was the STAMPEDE trial abiraterone comparison carried out?

Between November 2011 and January 2014, 1917 men joined the abiraterone comparison in STAMPEDE.

- 957 people were in group A. They received standard hormone therapy with or without radiotherapy
- 960 people were in group G. They received standard hormone therapy (with or without radiotherapy) plus abiraterone (4 pills a day) plus prednisolone (a steroid to help with the side-effects of abiraterone), until the disease got worse or they had been on abiraterone for two years.

So far, we have followed up how people are doing for around three years and four months. We wanted to see if abiraterone improved how long men lived, compared to the standard treatment. We looked at the side-effects people had. We also wanted to see whether abiraterone increased the time until the treatment stopped working.

What did the STAMPEDE trial abiraterone comparison find?

The STAMPEDE trial found that people who had abiraterone plus standard hormone therapy lived longer on average than people who had standard hormone therapy.

76% of men in group A were alive three years after starting hormone therapy, compared to 83% in group G (the abiraterone group). We have enough information to be confident that abiraterone increases how long men live for.

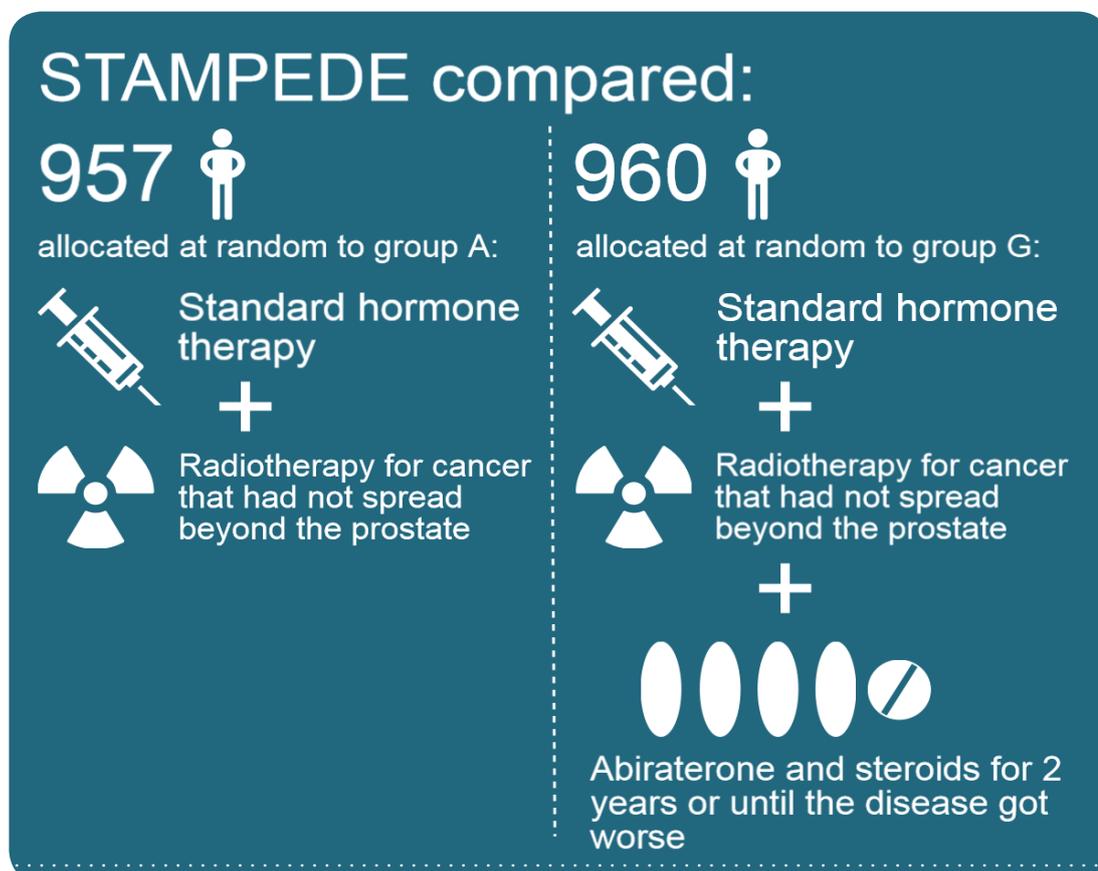
Abiraterone also:

- delayed the time until the first sign that treatment had stopped working by about 14 months. Hormone therapy was still working for 45% of men in group A three years after starting, compared to 75% in group G (the abiraterone group).
- delayed the disease getting worse
- reduced the risk of having bone problems

One in three men in group A (the standard hormone treatment) reported having a severe side-effect, compared to one in two men in group G (abiraterone plus standard hormone

therapy). The table on the next page shows the most common severe side-effects men reported.

One in five of the men who stopped taking abiraterone say they did so because of side-effects.



Most common severe side-effects:

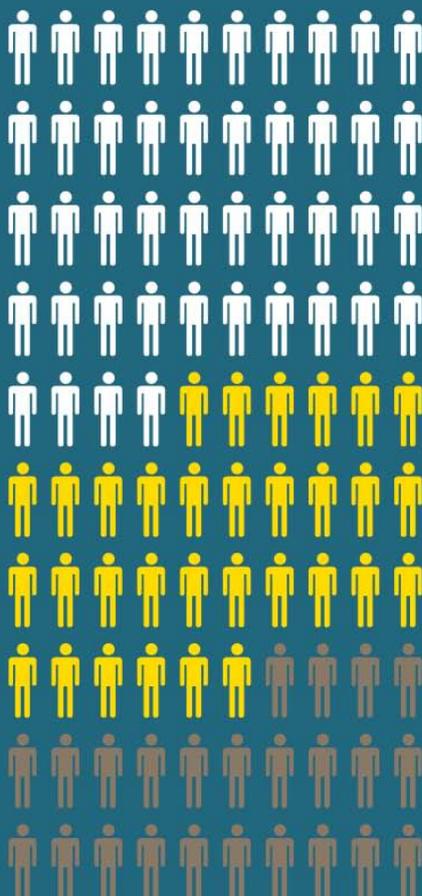
	Group A	Group G
Hot flushes and / or impotence	14 in 100 men	14 in 100 men
Problems with joints (for example, arthritis)	5 in 100 men	7 in 100 men
Cardiovascular problems such as hypertension or heart problems	4 in 100 men	10 in 100 men
Diarrhoea, stomach ache, constipation or sickness	4 in 100 men	5 in 100 men
Problems with tiredness, fever or weakness	3 in 100 men	5 in 100 men
Breathlessness or colds or flu	2 in 100 men	5 in 100 men
Abnormal results from lab tests checking if their livers were working properly	1 in 100 men	7 in 100 men

STAMPEDE found:

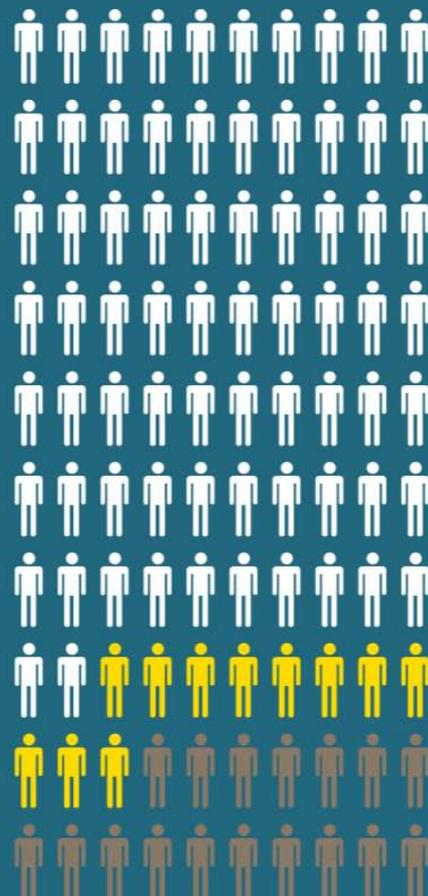
After 3 years



Standard hormone therapy



Abiraterone + standard hormone therapy



Alive without disease coming back



Alive with disease come back



Dead from any cause

What do these results mean?

What do these results mean for you?

These results are not directly relevant to your future treatment, as they only apply to men starting long-term hormone therapy for the first time.

If you were randomised to the abiraterone group, and are still on abiraterone, please keep taking it until your doctor tells you to stop.

Whichever treatments you are receiving as part of STAMPEDE, please keep coming to your appointments. We are still very interested in how you do. This information will be useful to answer questions about long-term effects.

What do these results mean for other people?

These results suggest that those people with prostate cancer who are starting long-term hormone therapy for the first time are likely to benefit from abiraterone. Abiraterone is not suitable for everyone, but men like those in STAMPEDE may benefit.

What difference will these results make?

These results could help improve how future patients with prostate cancer are treated.

Abiraterone is not yet licensed for use before standard hormone therapy stops working. The company who makes the drug will need to submit an application to the drug regulator, who will look at the evidence to see if abiraterone is safe and effective enough to use outside of clinical trials.

Abiraterone is an expensive drug, so the NHS will need information on whether the benefits outweigh the costs. They will look at the STAMPEDE results, together with other evidence, to decide whether it should be used more widely.

The STAMPEDE trial is still carrying on, and is looking at a number of other approaches that might help improve treatment of men with prostate cancer.

Conclusion

Thank you for taking part in the STAMPEDE trial. You are helping us to answer important questions about how to treat people with prostate cancer. The results from early comparisons in STAMPEDE are already helping men with prostate cancer. We hope that these latest results will help patients in the future.

Further information

We have made a short film about these results. You can watch it online bit.ly/STAMPEDEfindings. You can find out more about the STAMPEDE trial at www.stampedetrial.org

If you have any questions about the STAMPEDE trial, please speak to your doctor or research nurse.

Prostate Cancer UK have specialist nurses who can help answer any questions you have about prostate cancer. You can call them on 0800 074 8383.

This study is officially known as STAMPEDE: Systemic Therapy in Advancing or Metastatic Prostate Cancer: Evaluation of Drug Efficacy (MRC PR08). It is registered on clinical trials databases, where you can find out more information. Its registration numbers are:

- www.ISRCTN.com: ISRCTN78818544 DOI 10.1186/ISRCTN78818544
- www.ClinicalTrials.gov: NCT00268476
- EUDRACT: 2004-000193-31

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For more information about clinical trials, visit <http://bit.ly/abouttrials>

**This research is important.
Thank you for helping us to
understand more about how
to treat prostate cancer.**