

Results of the Prostate MRI imaging study (PROMIS)

Thank you

Thank you for taking part in the PROMIS study. You have helped us to answer an important question about how best to diagnose prostate cancer. This will help men in the future.

What was PROMIS about?

PROMIS was testing how best to diagnose prostate cancer. It compared the current standard approach, Trans-rectal Ultrasound (TRUS) biopsy, with a MRI scan and a Template Prostate Mapping (TPM) biopsy. It aimed to see if having an MRI scan first could help doctors decide which men do not need to have a biopsy.

Why was the PROMIS study needed?

We did the PROMIS study because using TRUS biopsies to diagnose prostate cancer has drawbacks. TRUS biopsies miss some important cancers. They can also cause side-effects, such as pain, bleeding, infections and problems urinating. The researchers also hoped that MRI scans could help doctors work out who does not need a biopsy.

Who took part in PROMIS?

Men from 11 hospitals in England and Wales took part in the PROMIS study. Men could take part in PROMIS if their doctor had a clinical suspicion that they may have prostate cancer and they had never had a prostate biopsy before. This suspicion could be based on a number of things including:

- a raised PSA level found in a blood test
- symptoms (such as a frequent need to urinate)
- ethnicity (African-Caribbean men are at higher risk of prostate cancer than white men)
- previous family history of prostate cancer in a father or brother

What tests did PROMIS use?

Trans-rectal Ultrasound (TRUS): a TRUS biopsy involves putting a small ultrasound device into a man's back passage, and using the images from it to guide needles to take 10 to 12 small samples from his prostate.

Multi-parametric MRI scan (MP-MRI): This type of scan uses magnetism and radio waves to build up a detailed picture of the prostate and surrounding tissues.

Template Prostate Mapping (TPM): a TPM biopsy involves putting a template with holes approximately 5mm apart over the area of skin behind the testicles. Multiple needles are put through the different holes in the template to take a larger number of small samples from throughout the prostate.

Men had to agree to have all 3 tests and be suitable for the tests.

How was the study carried out?

Between May 2012 and December 2015, 740 men agreed to take part, but not all men had all 3 tests. 576 men had

- a MRI scan
- followed by a:
- TPM biopsy
 - TRUS biopsy

The biopsies were carried out under general anaesthetic.

Researchers who conducted each test were not aware of the results of the other tests until all tests had been completed. After the results were carefully recorded for each test, all men were informed of all their results.

We then compared the results for MRI scans and TRUS biopsies to the TPM biopsy, which is the most accurate test. We wanted to see how good the tests were at correctly identifying who had clinically important prostate cancer, and who did not.

What did PROMIS find?

- TRUS biopsies correctly detected important cancer in about half (48%) of men with important prostate cancers. They missed half of important cancers.
- MRI scans correctly detected important cancer in 93% of men with important prostate cancers.
- MRI scans were less good at identifying who did not have clinically important prostate cancer. The scans only got this right in less than half (41%) of men who did not have important cancer.

What do these results mean?

Because MRI scans correctly identified nearly all men who had clinically important prostate cancer, doctors can use these results to decide who does not need a biopsy. This could help around 1 in 4 men safely avoid having a biopsy, and the side-effects that come with it.

Men whose MRI scan shows signs of cancer will still need to have a biopsy, as MRI alone tends to over-diagnose important prostate cancer.

What difference will these results make?

The National Institute for Health and Care Excellence (NICE) is looking at the PROMIS results. They will decide whether to recommend that hospitals in England offer men with a suspicion of prostate cancer a MRI scan to decide if they need a biopsy.

Conclusion

Thank you for taking part in PROMIS. You have helped us to answer an important question about how to diagnose prostate cancer. We hope that these results will mean that some men in the future will be able to avoid having unnecessary biopsies.

Using MRI scans before biopsy to diagnose prostate cancer

could help more than a quarter of men avoid an unnecessary TRUS biopsy...



... and the side-effects of biopsies



Further information

If you have any questions about the PROMIS study and its results, you can speak to the Prostate Cancer UK specialist nurses. You can call them on 0800 074 8383.

There is more information about the PROMIS study http://www.ctu.mrc.ac.uk/our_research/research_areas/cancer/studies/promis/

You can find a link to the full scientific results here http://bit.ly/promis_results

PROMIS is registered with the ISRCTN registry. The registration number is 16082556. You can see more details about the trial <http://www.isrctn.com/ISRCTN16082556>