Proper Understanding of Recurrent Stress Urinary Incontinence Treatment in women:
A randomised controlled trial of endoscopic and surgical treatment

Frequently Asked Questions (FAQ's) for patients

Contents

1. Study design

Question 1.1	**Why are you doing the PURSUIT study?** **What is the aim of this study?**
Response	Unfortunately, symptoms can come back after women have received treatment for stress urinary incontinence (SUI), this is called recurrent SUI. In some cases, symptoms may never have gone away after treatment, this is called persistent SUI. We do not know which of the available NHS treatments is best for women who have already had an operation or bulking injections for SUI. The aim of this study is to find out whether a surgical operation or endoscopic bulking injections are better for treating recurrent or persistent SUI.

Question 1.2	**What does the study involve?** **How many women will be asked to take part?**
Response	250 women will be recruited to the PURSUIT study. Equal numbers of women will join an endoscopic bulking injection group or a surgical operation group. Which group women join will be decided by chance (in a process called randomisation). Women in the surgical operation group will decide which operation to have in consultation with their doctor. Women will receive their treatment and aftercare at hospital, as they would during normal NHS care and will be asked to complete a questionnaire booklet at the start of the study and again 6 months, 1, 2 and 3 years later. The questionnaires cover general health, urinary symptoms and the effect of those symptoms on everyday life and sex life. We will audio-record consultations where the PURSUIT study is discussed with women and interview some women to see how research is explained and understand how women manage after their treatment.

Question 1.3	**Does the PURSUIT study comply with Baroness Cumberlege's recommendations detailed in her report "First Do No Harm"?**
Response	Yes. The Independent Medicines and Medical Devices Safety (IMMDS) Review, chaired by Baroness Julia Cumberlege, is fundamental to the PURSUIT trial going forward. The PURSUIT study was designed knowing that this report was in development so the design was intentionally flexible to ensure that we would be able to comply fully with the recommendations once the report was published. All our study documents, including the protocol fully reflect this. While the IMMDS Report included / counted bulking agent injections among non-surgical conservative treatment options, PURSUIT had been more conservative and had considered such injections to be more invasive interventions, that require robust scientific evidence on their therapeutic outcome. Our study had set out to assess safety and efficacy of endoscopic injections, in comparison to those of more established surgical treatment options, for women with recurrent stress urinary incontinence.

Question 1.4	**Is the PURSUIT study a commercial study?** **Is there any industry involvement in PURSUIT?**
Response	No. PURSUIT is a non-commercial study and is independent of any industry input and is entirely funded by the National Institute for Health Research (NIHR). The Chief Investigator (lead applicant) and all co-applicants were asked to declare any conflicts, or potential conflicts, of interest (COI) for undertaking this research at the application stage of the study, none were declared. The study requests declaration of potential conflicts of interest annually from all investigators. When joining the Trial Steering Committee (TSC), and throughout the lifetime of the study, TSC members (independent and non-independent) are asked to disclose any competing interests. These may include financial matters, involvement in other trials or intellectual investment. None have been declared. All the surgeons and staff involved in the PURSUIT study are employed by the NHS and all treatments in the study are done as part of NHS care (not private treatments).

2. Study approvals

Question 2.1	**Who has reviewed and approved the study?**
Response	Like all research that is led from England and involves the NHS and Health and Social Care (HSC), the PURSUIT study has been reviewed and approved by the Health Research Authority (HRA). HRA approval encompasses governance and legal compliance and an independent ethical opinion by a Research Ethics Committee (REC). The REC for PURSUIT is South West - Frenchay Research Ethics Committee.

Question 2.2	**Has anyone else reviewed the study?** **Were patients asked about the design of the study?**
Response	Yes. PURSUIT had very strong Patient and Public Involvement (PPI) during the design phase of the study. PPI input was invaluable in designing a Randomised Controlled Trial (RCT) which would be acceptable to this patient group. That is, ensuring that patients would not be randomised to a specific surgical treatment but would have a choice. PURSUIT also has an active Patient Advisory Group (PAG) who meet throughout the whole duration of the study. This group have helped with the development of the study documents to ensure that they are easy to read and understand, and that the information is clear and transparent. The study Sponsor (North Bristol NHS Trust) has also scrutinised, and approved, all the study materials.

3. Eligibility (inclusion/exclusion)

Question 3.1	Who can participate in PURSUIT?
Response	Adult (18 years or older) women with recurrent or persistent SUI who have previously had an operation or bulking injection for it.

Question 3.2	I have urgency incontinence; can I take part in PURSUIT?
Response	If you have mixed urinary incontinence (leakage associated with both urgency and stress incontinence) you may take part in the study as long as the **stress incontinence is predominant**. Your healthcare team will assess this before you are invited to take part.

4. Taking part

- Please see the PURSUIT Participant Information Leaflet for further details about taking part in the study https://pursuit.blogs.bristol.ac.uk/taking-part/

Question 4.1	Can I see a copy of the Participant Information Leaflet?
Response	Yes. All women who are invited to take part will be provided with a copy of the Participant Information Leaflet (PIL). The study PIL is also available on the study website for anyone interested in finding out more about the study https://pursuit.blogs.bristol.ac.uk/taking-part/ The study PIL covers information regarding taking part in this research study. The PIL does not replace information provided to patients about the different treatment options for recurrent SUI. Details of each procedure will be provided, as per usual NHS care, by the patient's healthcare team (surgeon/nurse).

Question 4.2	What are the possible risks of participating?
Response	There is no additional risk to normal NHS practice of the endoscopic bulking injections or surgical operations, and neither are new or experimental. Women taking part will have the same risks as anyone having treatment for recurrent SUI. This includes the possibility that symptoms may not improve as much as women would like. The risks and benefits of each treatment will be explained by the doctors, and women will be provided with supporting information as per their hospital's normal care pathway.

Question 4.3	What are the possible benefits of participating?
Response	Some people favour being part of research studies because of the close contact with research staff and the opportunity to share their opinions and experiences of their condition and treatments. Women will be offered a £10 voucher for completing their questionnaire at 1 year and another £10 voucher for completing their questionnaire at 3 years.

5. Informed consent

Question 5.1	What is the consent process for taking part in PURSUIT?
Response	PURSUIT is a trial with voluntary participation. Patients are given the Participant Information Leaflet and time to read it. They have the opportunity to ask any questions and discuss the study fully with their surgeon. If they are happy they may take part, if they decide not to take part their treatment is not affected. All participants are asked to provide written informed consent to take part in the study.

Question 5.2	The Participant Information Leaflet does not fully explain all of the treatments/procedures – why not?
Response	The Participant Information Leaflet and consent forms for PURSUIT cover consent to take part in the study. This is not the same as a patient giving their consent for treatment. Patients who are considering the study will discuss treatment options offered in the study (the same as those offered by the NHS) with their surgeon as they would under normal NHS care. This discussion with their doctor may be supported by the usual information resources that each individual hospital or surgeon would usually use - this may be NHS Trust-specific leaflets or videos/animations describing each procedure, or it may be national information leaflets, for example those from NICE. Consent for the study and consent to have NHS treatment are both voluntary, fully informed and only done when the patient has the capacity to do it.

6. Study treatments (interventions)

Question 6.1	Which treatments are offered in the PURSUIT study?
Response	The treatments offered in the PURSUIT study are all standard NHS treatments available for recurrent or persistent SUI. Women outside of the PURSUIT study who seek treatment for recurrent or persistent SUI have the same treatment options available to them. All procedures offered in the study follow stringent UK national and international guidelines and all products used are CE-marked and being used for their intended and licensed purpose. The NHS only uses medical devices that are licensed by the Medicines and Healthcare products Regulatory Agency (MHRA). All products used in PURSUIT are MHRA (and FDA) approved. The PURSUIT study team are a group of doctors, nurses, and researchers. We do not re-assess NHS treatments but rely on the relevant regulatory bodies which allow those treatments in the NHS. NHS treatment options for recurrent or persistent SUI are: 1. Injections into the urethra to help it to seal when leaks might happen called **Endoscopic bulking injections**. The injections are done using a cystoscope to inspect the inside of the bladder and urethra. 2. A surgical operation; - A strip of the patient's own tissue (taken from the tummy area) is used to support the urethra (**autologous fascial sling**). - Stitches are used to lift the vagina so that it supports the urethra (**colposuspension**). - An implant device is placed around the urethra to gently squeeze it and prevent leaking (**artificial urinary sphincter)**. - A medical mesh tape is placed in the vagina to support the urethra (**midurethral tape**) e.g. TVT. **Note**: NHS rules restrict the use of mesh for vaginal surgery. At the time of writing (July 2020) use of midurethral tape for recurrent SUI **is not permitted** in the NHS or in PURSUIT.

Question 6.2	Is vaginal mesh (midurethral tape) being used in PURSUIT?
Response	No. There are specific rules from the NHS which regulate the use of mesh in vaginal surgery. The rules relevant at the time will be used for anyone wishing to consider this type of surgery. Currently (July 2020) midurethral tape is **not** a treatment option for recurrent SUI in the NHS or in PURSUIT. If, during the lifetime of the PURSUIT study, the use of midurethral tape for the treatment of recurrent SUI is permitted in the NHS, it will be a treatment option within the surgical arm of the study. It will still be the patient's decision whether to consider this as a treatment option within the surgical arm of the study.

Question 6.3	Why does some of the information about the PURSUIT study online say that mesh could be used?
Response	When a study/clinical trial is funded, it is normal for the funder (NIHR for PURSUIT) to publish information about the study on its website. The PURSUIT study was designed before the use of mesh was suspended in the UK and before the review into the use of mesh (IMMDS report) was conducted and published. When information on these pages is updated, it usually appears at the bottom of the page which has, understandably, led to some confusion as older information appears first. We have requested that the NIHR review the way that this information is displayed, and they have informed us that this will be addressed. https://fundingawards.nihr.ac.uk/award/17/95/03 The final study protocol will be published in a scientific journal.

Question 6.4	What are the success rates of each procedure/intervention/treatment?
Response	The success rate of each treatment for *recurrent* SUI is unknown. All published outcome rates from high-quality research refer to primary SUI treatment. It is for this reason that the study is being done and the results from this study will provide us with an answer to this important question.

Question 6.5	Are patients randomised to a specific surgical operation?
Response	No. Patients are randomised to either the endoscopic arm or the surgical arm. If a patient is randomised to the surgical arm, they will have a detailed discussion with their doctor about which operation(s) may be suitable for them. The patient will then be able to choose, with their doctor, which surgical procedure they have. This was a key discussion point during the design of the study. Both the co-investigators and the Patient and Public Involvement (PPI) group felt strongly that randomising patients to a specific surgical procedure would not be acceptable to patients or their doctors. This view was also supported by the Research Ethics Committee during their review of the study.

7. General questions

Question 7.1	Where is the study run from?
Response	This study is sponsored by North Bristol NHS Trust. The Bristol Randomised Trials Collaboration (as part of the Bristol Trials Centre) at the University of Bristol is responsible for managing the study. We aim to run the study in at least 20 NHS Hospitals across the UK.

Question 7.2	When is the study starting and how long is it expected to run for?
Response	The study started in April 2019 and will run for 6 years, until 2025.

Question 7.3	Who is funding the study?
Response	The National Institute for Health Research (NIHR) Health Technology Assessment (HTA) Programme (reference number: 17/95/03)

8. Contact details

Question 8.1	Who should I contact if I have questions or comments about the study that are not answered/addressed here?
Response	If you have further questions about the study please contact the PURSUIT Study Team by emailing us at: pursuit-trial@bristol.ac.uk If you have questions about your health and finding out whether you would be suitable to take part in the study, please contact your doctor to discuss this further. It may help if you take a copy of the PURSUIT Participant Information Leaflet with you when you visit your doctor. If you have any questions or comments about the different treatment options/devices offered in the NHS, please direct them to the appropriate regulatory authority or manufacturer.