Primary care management of lower urinary tract symptoms in men

Submission date 11/09/2017	Recruitment status No longer recruiting	[X] Prospectively registered
		[X] Protocol
Registration date	Overall study status	Statistical analysis plan
09/10/2017	Completed	[X] Results
Last Edited	Condition category	Individual participant data
03/02/2025	Urological and Genital Diseases	

Plain English summary of protocol

Background and study aims

More than 10% of older men experience the need to pass urine more frequently than usual and often find their sleep interrupted by having to go to the toilet during the night. Some will find that their urine flow rate has become slower, and some will experience loss of bladder control. Such problems are distressing for men, affect their work and social life, and are a common reason why men visit a general practitioner (GP) with over 60,000 attendances yearly across the UK. They firstly need reassurance that they are not suffering from cancer or any other sinister medical condition. GPs follow established procedures when considering signs of cancer or these more serious conditions, but they have no easily available assessment tools to identify other more common causes of lower urinary tract symptoms (LUTS), or to advise men about the best treatment options for symptom relief. Because of this, men have to be referred to hospital based urology specialists for tests and diagnosis. The aim of this study is to investigate the accuracy of a new decision aid for use by GPs to diagnose the cause of LUTS in men and to assist decisions in determining appropriate person centred treatment. The aim of the main PriMUS study is to create a practical and accurate 'decision aid' to help GPs find out the most likely cause of patients' lower urinary tract symptoms (LUTS). The GP will then use the decision aid so that they and the patient can choose the best treatment option together. Follow-up is to be conducted at approximately 3-6 months, collating the treatment and management decisions made as a result of these procedures.

Who can participate?

Men aged 16 and older who have a lower urinary tract symptoms.

What does the study involve?

All participants receive the same procedures; including index tests (standard care according to NICE guidance) and a reference test (completed at secondary care level if patient referred to urology). The results of the simple tests with results of urodynamics and identify which simple tests give best prediction of the urodynamic result.

What are the possible benefits and risks of participating?

Participants may benefit from having a very thorough investigation of their urinary symptoms within a few weeks of seeing their GP. This includes an urodynamics test, which is the gold

standard test for determining the cause of urinary symptoms and usually takes place once a patient has been referred to hospital. Symptoms might therefore be suitably managed in a shorter timeframe than usual, as a patient's GP will have all the information they need to make an accurate diagnosis. Patient's will receive a high street shopping voucher to a maximum value of £30, to cover any travel expenses incurred whilst taking part in the study. There are potential risks with undergoing the urodynamics test. After the test patient's may experience a mild stinging sensation when they pass urine for a few hours, or in some cases up to a day or so, but these symptoms usually improve quickly. They may also pass a little blood with the urine the first time they pass water. About 5% (five in a hundred) of patients who have this test get a bladder infection (cystitis) afterwards. If this happens the stinging will get worse and they may feel more unwell. If this occurs they should see their GP as soon as possible, and will probably be treated with a course of antibiotics. There is a small risk, (less than one in a hundred) of urine retention (inability to pass water) following the urodynamics test in men with difficulty emptying their bladders, although this rarely occurs. If patients are at all worried they should see their GP as soon as possible.

Where is the study run from?

This study is being run by Cardiff University (UK) and takes place in GP practices across England and Wales recruited from three main research hubs (Newcastle, Bristol and Wales).

When is the study starting and how long is it expected to run for? May 2017 to April 2021

Who is funding the study? National Institute for Health Research (UK)

Who is the main contact? Janine Bates, batesmj@cf.ac.uk

Contact information

Type(s)

Public

Contact name

Ms Janine Bates

Contact details

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT03520673

Protocol serial number

CPMS 36076

Study information

Scientific Title

Primary care management of lower urinary tract symptoms in men: Development and validation of a diagnostic and decision-making aid

Acronym

PriMUS

Study objectives

Current study hypothesis as of 12/03/2018:

The aim of the PriMUS study is to create a 'Clinical Decision Support Tool' to help GPs find out the most likely cause of patients' urinary symptoms, so that together they can choose the best management. It is believed that this will have many benefits such as getting to the right treatment sooner, avoiding unnecessary hospital visits, and getting those who need to be treated by a specialist there more quickly.

Original study hypothesis:

The aims of the PriMUS study is to create a 'decision aid' to help GPs find out the most likely cause of patients' urinary symptoms, so that together they can choose the best management. It is believed that this will have many benefits such as getting to the right treatment sooner, avoiding unnecessary hospital visits, and getting those who need to be treated by a specialist there more quickly.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Current ethics approval statement as of 12/03/2018:

Wales REC 6, 20/06/2017, ref: 17/WA/0155

Original ethics approval statement:

Wales REC 3, 20/06/2017, ref: 17/WA/0155

Study design

Non-randomized

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Lower urinary tract symptoms

Interventions

All patients receive the same treatment. They receive simple index tests, outlining NICE clinical guidance, and all receive the reference test urodynamics. The purpose of the study is to compare the results of all the index tests, with the results of urodynamics, to see whether the index tests can provide an accurate diagnosis and management decision for LUTS. GPs are sent the results of all the index tests and a recommendation for a management decision, to follow up the patient as appropriate. The participants' medical records are reviewed approximately 3-6 months after, to collate the management decision made by the GP.

Intervention Type

Other

Primary outcome(s)

Sensitivity and specificity of the diagnoses of detrusor overactivity, bladder outlet obstruction and detrusor underactivity estimated by the decision aid (using invasive urodynamics as the gold standard reference test).

Key secondary outcome(s))

- 1. Construction of a patient management algorithm to guide initial treatment for men with LUTS
- 2. Construction of a prototype online decision aid for use in primary care
- 3. Qualitative analysis of patients and clinicians views on the use of a LUTS decision aid in the primary care setting
- 4. Percentage change in referral rates to secondary care for men with LUTS
- 5. Estimation of costs / savings of implementation of the primary care LUTS decision aid both from a population and individual patient perspective

Completion date

30/04/2021

Eligibility

Key inclusion criteria

- 1. Men
- 2. Aged 16 years and over
- 3. Present to their GP with a main complaint of one or more lower urinary tract symptoms
- 4. Able and willing to give informed consent for participation in study
- 5. Able and willing to undergo all index tests and reference test, and complete study documentation

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

16 years

Sex

Male

Key exclusion criteria

Current exclusion criteria as of 12/03/2018

- 1. Neurological disease or injury affecting lower urinary tract function
- 2. LUTS considered secondary to current or past invasive treatment or radiotherapy for pelvic disease
- 3. Contraindications to urodynamics e.g. heart valve or joint replacement surgery within the last 3 months, immunocompromised/immunosuppressed.
- 4. Indwelling urinary catheter or intermittent self-catheterisation
- 5. Initial assessment suggests that clinical findings are suggestive of possible:
- 5.1. prostate or bladder cancer*
- 5.2. recurrent or persistent symptomatic UTI**
- 5.3. retention, e.g. palpable bladder after voiding renal impairment
- 6. Unable to consent in English or Welsh where a suitable translator is not available

Original exclusion criteria

- 1. Neurological disease or injury affecting lower urinary tract function
- 2. Past or current invasive treatment for LUT malignancy
- 3. Initial assessment suggests that clinical findings are suggestive of possible:
- 3.1. Prostate or bladder cancer*
- 3.2. Recurrent or persistent symptomatic UTI**
- 4. Unable to consent in English or Welsh where a suitable translator is not available
- *According to standard NHS cancer pathways. If deemed unlikely, then eligible for study participation.
- **If UTI successfully treated but LUTS remain, then eligible for study.

Date of first enrolment

19/02/2018

Date of final enrolment

31/12/2020

Locations

Countries of recruitment

United Kingdom

England

Wales

Vauxhall Surgery

Vauxhall Ln Chepstow United Kingdom NP16 5PZ

Study participating centre Bellevue Surgery

Bellevue Terrace, Newport United Kingdom NP20 2WQ

Study participating centre North Celynen Practice

Ashfield Rd Newbridge Newport United Kingdom NP11 4RA

Study participating centre Greenmeadow Surgerydge

Greenmeadow Way Cwmbran United Kingdom NP44 3XQ

Study participating centre Malpas Brook Health Centre

107 Malpas Rd Newport United Kingdom NP20 5PJ

Study participating centre St Davids Clinic

Belle Vue Terrace Newport United Kingdom NP20 2LB

Study participating centre Nantgarw Road Medical Centre

4 Beddau Way CaerphillyK United Kingdom CF83 2AX

Study participating centre St Paul's Clinic

Palmyra Place Newport United Kingdom NP20 4EJ

Study participating centre Clifton Surgery

151-155 Newport Rd Cardiff United Kingdom CF24 1AG

Study participating centre The Practice of Health

31 Barry Road Barry United Kingdom CF63 1BA

Study participating centre Stanwell Surgery

Stanwell Road Penarth Vale of Glamorgan United Kingdom CF64 3XE

Llan Healthcare

Llan Healthcare Maelfe Llanedeyrn Cardiff United Kingdom CF28 9PN

Study participating centre Llandaff and Pentyrch Surgery

19a High Street Llandaff Cardiff United Kingdom CF5 2DY

Study participating centre Ely Bridge Surgery

23 Mill Road Ely Cardiff United Kingdom CF5 4AD

Study participating centre Roath House Surgery

100 Pen-Y-Lan Rd Cardiff United Kingdom CF23 5RH

Study participating centre Llandaff North Medical Centre

99 Station Rd Cardiff United Kingdom CF14 2FD

Study participating centre Whitchurch Village Practice

Park Road Surgery

Park Road Whitchurch Cardiff United Kingdom CF14 7EZ

Study participating centre Rumney Primary Care Centre

Barmouth Road Rumney Cardiff United Kingdom CF3 3LG

Study participating centre Llwyncelyn/Hollybush Practice

Park Road
Whitchurch
Cardiff
United Kingdom
CF14 7EZ

Study participating centre Ashgrove Surgery

Morgan Street Pontypridd United Kingdom CF37 2DR

Study participating centre Cynon Vale Medical Practice

8 Cardiff Road Mountain Ash United Kingdom CF45 4EY

Study participating centre Cwm Gwyrdd Medical Centre

High Street

Gilfach Goch United Kingdom CF39 8TJ

Study participating centre Penygraig Surgery

George Street
Penygraig
Tonypandy
United Kingdom
CF40 1QN

Study participating centre Keir Hardie Health Park Practice 3

Aberdare Rd Merthyr Tydfil United Kingdom CF48 1AZ

Study participating centre The Foundry Town Clinic

74 Monk Street Aberdare United Kingdom CF44 7PA

Study participating centre Oaklands Surgery

13 Oakland St Bedlinog Treharris United Kingdom CF46 6TE

Study participating centre St John's Medical Practice

Mid Glamorgan High St Aberdare United Kingdom CF44 7DD

Study participating centre Pont Newydd Medical Centre

Aber-Rhondda Rd Porth United Kingdom CF39 0LD

Study participating centre St Andrews Surgery

De Winton Street Tonypandy Rhondda Cynon Taff United Kingdom CF40 2QZ

Study participating centre Swarland Avenue Surgery

2 Swarland Avenue Benton Newcastle upon Tyne United Kingdom NE7 7TD

Study participating centre Redburn Park HC

15 Station Road Percy Main North Shields United Kingdom NE29 6HT

Study participating centre 49 MA Surgery

49 Marine Avenue Whitley Bay United Kingdom NE26 1NA

Study participating centre Park Rd MP

93 Park Rd Wallsend United Kingdom NE28 7LP

Study participating centre West Farm Surgery

31 West Farm Avenue Longbenton Newcastle upon Tyne United Kingdom NE12 8LS

Study participating centre Cheviot MG

2 Padgepool Pl Wooler United Kingdom NE71 6BL

Study participating centre Alnwick Medical Group

Consulting Rooms Infirmary Drive Alnwick United Kingdom NE66 2NR

Study participating centre Well Close Surgery

Well Close Square Berwick-upon-Tweed United Kingdom TD15 1LL

Study participating centre Belford Surgery

Croft Field Belford United Kingdom NE70 7ER

Study participating centre Glendale MG

Cheviot Primary Care Centre Padgepool Place Wooler United Kingdom NE71 6BL

Study participating centre Union Brae Surgery

Tweedmouth Berwick-upon-Tweed United Kingdom TD15 2HB

Study participating centre Coquet Medical Group

Broomhill Health Centre Hadston Road South Broomhill Morpeth United Kingdom NE65 9SF

Study participating centre Corbridge Surgery

Newcastle Rd Corbridge United Kingdom NE45 5LG

Study participating centre Burn Brae Surgery

Hexham Primary Care Centre Corbridge Road Hexham United Kingdom NE46 1QJ

Study participating centre Branch End Surgery

Stocksfield United Kingdom NE43 7LL

Study participating centre Humshaugh & Wark Surgery

1 E Lea Humshaugh Hexham United Kingdom NE46 4BU

Study participating centre White Medical Group

Ponteland Primary Care Centre Meadowfield Ponteland Newcastle upon Tyne United Kingdom NE20 9SD

Study participating centre Bellingham Practice

Bellingham Hexham United Kingdom NE48 2HE

Study participating centre Sele Medical Practice

Hexham Primary Care Centre Corbridge Road Hexham United Kingdom NE46 1QJ

Study participating centre Village Medical Group

Dudley Ln Cramlington United Kingdom NE23 6US

Study participating centre Netherfield House

Station Rd Seghill Cramlington United Kingdom NE23 7SE

Study participating centre Kingswood Healthcentre

Alma Road Kingswood Bristol United Kingdom BS15 4EJ

Study participating centre Cadbury Heath Health Centre

Parkwall Road Cadbury Heath Bristol United Kingdom BS30 8HS

Study participating centre Hanham Health

Whittucks Road Hanham Bristol United Kingdom BS15 3HY

Close Farm Surgery

47 Victoria Road North Common Bristol United Kingdom BS30 5JZ

Study participating centre Westbury on Trym Surgery

Westbury Hill Westbury On Trym Bristol United Kingdom BS9 3AA

Study participating centre Greenway Community Practice

Graystoke Avenue Southmead Bristol United Kingdom BS10 6AF

Study participating centre Fallodan Way Medical Practice

13 Fallodon Way Henleaze Bristol United Kingdom BS9 4HT

Study participating centre Monks Park Surgery

24 Monks Park Avenue Horfield BS7 0UE Bristol United Kingdom BS7 0UE

Tyntesfield Medical Group (Backwell Surgery, Brockway Surgery, Long Ashton Surgery, Tower House Medical Centre)

Brockway Medical Centre 8 Brockway Nailsea Bristol United Kingdom BS48 1BZ

Study participating centre Heart of Bath Medical Partnership

Oldfield Surgery 45 Upper Oldfield Park Bath United Kingdom BA2 3HT

Study participating centre West Walk Surgery

21 West Walk Yate Bristol United Kingdom BS37 4AX

Study participating centre Courtside Surgery

Kennedy Way Yate Bristol United Kingdom BS37 4DQ

Study participating centre Frome Valley Surgery

2 Court Rd
Frampton Cotterell
Winterbourne
Bristol
United Kingdom
BS36 2DE

Sponsor information

Organisation

Cardiff University

ROR

https://ror.org/03kk7td41

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created Date added Peer reviewed? Patient-facing?
Results article		01/01/2025 03/02/2025 Yes No
Protocol article	protocol	30/06/2020 02/07/2020 Yes No

HRA research summary 28/06/2023 No No

Participant information sheet Participant information sheet 11/11/2025 No Yes