



The OPEN Trial: Summary Information for Clinicians and Local Research Staff

- Aim:** For men with recurrent bulbar urethral stricture is **open** urethroplasty better than **endoscopic** urethrotomy for symptom relief and freedom from recurrence.
- Design:** Pragmatic head-to-head randomised superiority trial set within routine care in the NHS.
- Target patient group:** Men with recurrent bulbar urethral stricture (at least one previous intervention for bulbar stricture). Total sample size = 500 men.
- Trial interventions:** Remote computerised random allocation between urethroplasty (type of reconstruction decided by surgeon) and optical urethrotomy (according to standard practice by operating surgeon and may include subsequent intermittent self-dilatation according to local practice).
- Trial follow-up:** Standard hospital clinic follow up at 3, 12 and 24 months (end of active trial participation) including uroflowmetry. Participants will receive a standard short patient-reported outcome questionnaire direct from the trial office every three months for two years for web or paper-based completion.
- Measured outcomes:** Burden of symptoms over the 24 months after intervention (primary); cost-effectiveness over 24 months (primary); rates of stricture recurrence and re-intervention (secondary); improvement in measured urine flow rate (secondary).
- Recruiting patients:** If you see a man in clinic with symptomatic recurrent bulbar stricture please outline the treatment uncertainty and need for the trial and ask if he would like to discuss possible participation further. If positive either contact local trial staff immediately so he can be seen straight away, or record his preferred contact details and notify local trial staff as soon as possible.
- Local trial contact:** [site to complete]
- Trial website:** <http://www.opentrial.co.uk>
- Central trial office:** Chief Investigator: Robert Pickard; Trial Manager: Rachel Stephenson
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- Trial registrations:** ISRCTN 98009168; NIHR Portfolio 13507; NHS REC 12-NE-0343; NHS R&D CSP 112891; Local R&D [site to complete].