

SYNOPSIS

Open urethroplasty or endoscopic urethrotomy for recurrent bulbar urethral stricture



How to get involved

If you would like to participate as a recruitment site contact Trial Manager Rachel Stephenson at the OPEN trial office in Newcastle upon Tyne

✉ opentrialoffice@newcastle.ac.uk or ☎ 0191 2083819

Alternatively, you can contact the Chief Investigator, Professor Robert Pickard

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OPEN – the question

Is open urethroplasty more clinically effective and cost-effective than standard endoscopic urethrotomy for men with recurrent bulbar urethral stricture?

Background

Recent advances in open bulbar urethroplasty techniques such as the use of oral mucosal grafts and reduced hospital stay have widened its potential for use as an option for men with recurrent bulbar strictures. Endoscopic urethrotomy is the standard treatment as it is a straightforward, short, minimally invasive procedure but the stricture recurrence rate is 50% at two years. This compares with a 10% recurrence rate for open urethroplasty although a two week period of catheterisation is required post-operatively. Expert opinion and healthcare activity data suggest that open urethroplasty is underutilised. The OPEN trial seeks to define the best treatment option for men with recurrent bulbar stricture in the UK NHS setting.

Trial design

Pragmatic, head-to-head, randomised superiority trial set within routine care in the NHS aiming to recruit 500 participants and report in March 2015.

Outcomes

Primary

- Burden of lower urinary tract symptoms over 24 months after intervention
- Cost-utility over 24 months after intervention

Secondary

- Rates of stricture recurrence and re-intervention
- Improvement in maximum urine flow rate
- Comparative harms

Measurements

Patient-reported

- Symptom and quality of life questionnaire at baseline, immediately before intervention, immediately after intervention, then 3, 6, 9, 12, 18 and 24 months after intervention.

Site-reported

- Cost questionnaire 6, 12, 18 and 24 months
- Case report form at baseline, at the time of intervention, and at 3, 12 and 24 months after intervention
- Urinary flow rate at 3, 12 and 24 months

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