Multicentre Clinical Trials – Trauma & Orthopaedic Surgery

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Professor of Orthopaedic Surgery
Orthopaedic Surgical Trials Lead, Royal College of Surgeons
Surgical research or comic opera: questions, but few answers

“Cynics might even claim that the personal attributes that go to make a successful surgeon differ from those needed for collaborative multicentre research.”

Richard Horton
The Lancet, London, UK
The evidence base for orthopaedics and sports medicine

Scandalously poor in parts

L Stefan Lohmander professor¹, Ewa M Roos professor²
Address four main areas:

- Culture
- Infrastructure
- Research Priorities
- Engagement with stakeholders
Recruitment to surgical trials 2016

Breakdown of 25,746 patients recruited

Trauma and Orthopaedics 19.68%
Cardiothoracic 20.46%
Upper GI 20.35%
Colorectal 16.78%
Plastics and Hand 3.39%
Head and Neck 2.82%
Vascular 0.54%
Urology 4.59%
Breast 11.39%
The ProFHER trial

Funding: This pragmatic multicentre randomised trial was supported by UK NIHR - Health Technology Assessment award 06/404/53.

The views and opinions expressed herein are those of the authors and do not necessarily reflect those of the National Institute for Health Research, the National Health Service, or the Department of Health.

• Trial registration: ISRCTN50850043
• Trial Governance: TSC & DMEC
Proximal Humeral Fractures

- 5-6% of all fractures in adults
- Incidence increases with age (mean age ~ 70 years)
- Female:male = 2:1

- Displaced fractures = Treatment uncertainty
- Trend to increased use of surgery, not evidence based!
Recruitment targets

Sample size:

- Recruitment: 250 participants

From 32 Centres, completed recruitment in April 2011

2 Year follow up completed in April 2013

5 Year follow up completed in April 2016
Getting centres research ready

ProFHER: extension projections

Number of participants

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Conclusion

Current surgical practice does not result in a better outcome for majority of adults with displaced proximal humeral fractures involving the surgical neck, and does not support the trend to increased surgery.

Surgery is not cost effective in the UK setting.
Surgical vs Nonsurgical Treatment of Adults with Displaced Fractures of the Proximal Humerus
The PROFHER Randomized Clinical Trial

Amar Rangan, Helen Handoll, Stephen Brealey, Laura Jefferson, Ada Keding, Belen Corbacho Martin, Lorna Goodchild, Ling-Hsiang Chuang, Catherine Hewitt, David Torgerson, for the PROFHER Trial Collaborators

JAMA March 10, 2015 Volume 313, Number 10: pages 1037-1047
Five-year follow-up results of the PROFHER trial comparing operative and non-operative treatment of adults with a displaced fracture of the proximal humerus


Impact

• NICE guidance on fracture management published Feb 2016:
  • Recommendations based on PROFHER Trial for proximal humeral fracture management:

  “For adults (skeletally mature) with displaced low energy proximal humerus fractures: offer non-surgical management for definitive treatment of uncomplicated injuries

  consider surgery for injuries complicated by an open wound, tenting of the skin, vascular injury, fracture dislocation or a split of the humeral head.”
Identify research priorities

• Hip & Knee OA
• Shoulder surgery
• Fragility fractures

BMJ Open  Research priorities for shoulder surgery: results of the 2015 James Lind Alliance patient and clinician priority setting partnership

Amar Rangan,¹ Sheela Upadhaya,² Sandra Regan,³ Francine Toye,⁴ Jonathan L Rees⁵
• More severe fractures in patients >65 years of age
• Effectiveness of reverse shoulder arthroplasty
• Comparators: Hemiarthroplasty and non-surgical treatment
UK FROST
Frozen Shoulder Trial

South Tees Hospitals NHS Foundation Trust

National Institute for Health Research
UK FROST Recruitment Progress

Figures up to 20 November 2017
Summary

- Culture, infrastructure, research priorities
- Growing portfolio of surgical trials
- Robust recruiting network for T&O
- T&O Trials can deliver to time & target
- YTU has played a major role to get us to where we are today!