By-Band-Sleeve

BUILDING EVIDENCE TOGETHER

Newsletter

August 2017

Background

A recent Cochrane review of surgery for weight loss [1] highlights the need for high-quality randomised trials to establish evidence for types of surgery. However, RCTs in surgery are often considered to be difficult-to-do because of preferences that prohibit randomisation. Here we present the design of the UK NIHR funded By-Band-Sleeve study (BBS).

Hypothesis

The By-Band-Sleeve study will compare the effectiveness, cost-effectiveness and acceptability of Band versus Bypass versus Sleeve surgery for treatment of severe and complex obesity. We will test the following joint hypotheses:

Bypass is non-inferior to Band with respect to excess weight loss of more than 50% at three years and that Bypass is superior to Band with respect to HRQOL at 3yrs.

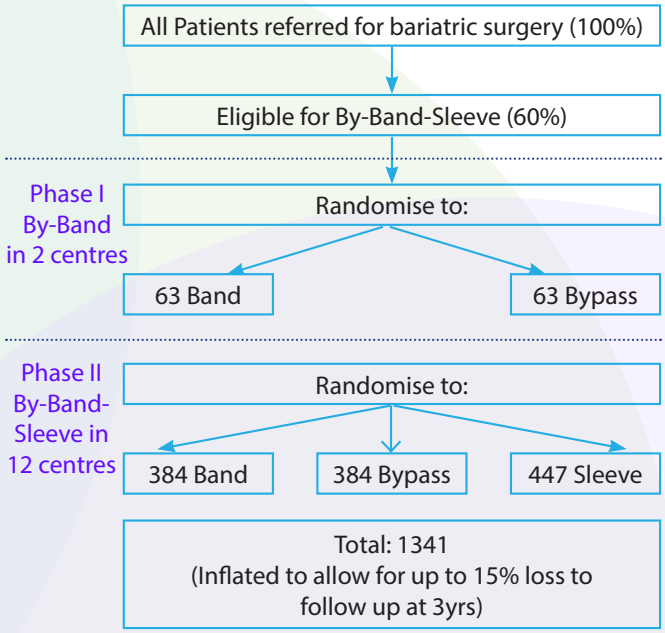
Sleeve is non-inferior to Band with respect to excess weight loss of more than 50% at three years and that Sleeve is superior to Band with respect to HRQOL at 3yrs.

Sleeve is non-inferior to Bypass with respect to excess weight loss of more than 50% at three years and that Sleeve is superior to Bypass with respect to HRQOL at 3yrs.

Study Design

- By-Band-Sleeve is a multi-centre RCT with an internal pilot phase.
- The first phase (in two centres) included a recruitment intervention to establish if randomisation between adjustable-gastric-band and Roux-en-Y-gastric-bypass (By-Band study) was possible.
- The study is now in phase II and recruiting in 11 centres (soon to be 12).
- The study was adapted at the end of phase I to include a third group, sleeve gastrectomy (By-Band-Sleeve).
- The study also includes a 'non-randomised' cohort of patients, who are also followed to 3yrs.

Study Schema



How has being a PI in the BBS study changed your practice?

Mr Nick Carter
PI and Lead Surgeon
Queen Alexandra Hospital, Portsmouth

"It has opened my mind and completely changed the way I talk to all my patients about all the operations – in particular talking them through side effects and the advantages and disadvantages of each procedure. I think this can only be good for patients."

Study Progress

- Screened n = 4116
- Eligible n = 2721
- Approached n = 2423
- Consented n = 834
- Randomised n = 827
- Surgery complete n = 578
- Reached 6 months n = 650
- Reached 12 months n = 452
- Reached 24 months n = 206
- Reached 36 months n=119

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References

[1] Colquitt JL, Pickett K, Loveman E, Frampton GK. Surgery for weight loss in adults. The Cochrane database of systematic reviews. 2014;8:CD003641

What's it like to be a PI in the BBS study?

Mr James Byrne
PI and Lead Surgeon
University Hospital Southampton

"We have seen dramatic changes in bariatric surgical practice over the last 15 years, both in the UK and worldwide. I, like many, enthusiastically embraced the gastric band then the bypass and latterly the gastric sleeve. In preoperative consultations with patients I have confidently advised them to receive each of these procedures: band is simple and straight forward and works, bypass may be better suited for diabetics, sleeve is also simple if there are sceptical views about the band. I have dealt with patients experiencing side effects from all three procedures which can be difficult to manage (particularly after bypass and sleeve) and other patients with poor weight loss after not only the gastric band, also the gastric bypass and sleeve.

I honestly gave the information based on my views, experience and what I heard at meetings/read. The information, however, was mostly from single centre retrospective studies and opinion based. There is a need to give our patients reliable and relevant information about the comparative effectiveness and side effects of the differing procedures. By far the best way to gather this information in a scientific way is through well-designed and conducted multi-centre pragmatic randomised controlled trials.

We would be shocked if our doctor recommended a new drug, to us or a family member, for a chronic condition like heart failure, that had not been rigorously evaluated, tested and compared to other existing drugs, yet that is precisely how bariatric surgery has evolved and severe obesity is a chronic condition that needs to be treated better.

Clearly there is a balance to be struck between unfettered innovation where we do not learn because of the chaotic way in which practice develops (and potentially harms patients), and over regulated systems that stifle improvements in care. Whilst registries such as BOLD, LABS, NBSR form important contributions – there is still a need for RCTs.

Eleven UK centres have successfully worked together in By-Band-Sleeve (BBS). I believe passionately in, and am proud to be associated with this. I believe that BBS will inform UK and international bariatric surgical practice for many years to come. Being a BBS investigator has been a challenging, enjoyable (mainly) and a fascinating journey from the initial meetings through to where we are today.

Ensuring that everyone can see the value of what the study is trying to achieve has been challenging; we have had to face the firmly held but not well evidence-based opinions of colleagues and some patients, many of whom may have firmly held preferences. Conveying equipoise to patients, successfully recruiting and then seeing how the study is being delivered has been surprising. I have learnt that outcome is not all about the weight; a happy patient in control of their behaviour, is now to me, the most important outcome of surgery.

The negotiation skills in recruiting patients and not just accepting preferences at face value has been hugely beneficial across the entirety of my clinical practice.

As we enter the final phase of recruitment (about 500 to go) I am excited to await the results. I genuinely do not know which of these procedures will be the winner, and in one sense it's not what's the most important. We will have a very well characterised cohort of patients, reflecting the reality of UK bariatric surgical practice, and I look forward to using the results of this study to better inform my patients about their choices in the future."

Study Milestones

- Grant open Jan 2012
- First centre opens Nov 2012
- Review of phase I Dec 2013
- Funder approval to move to phase II Mar 2014
- First phase 2 centre opens Jul 2014
- Study adapted to include sleeve Aug 2015
- 1ST patient reaches 3yr follow-up Jan 2016
- Recruitment due to end summer 2018
- Final follow-up summer 2021
- Results available early 2022

Chief Investigator: Jane Blazeby
Lead Surgeon: Richard Welbourn
Study Manager: Graziella Mazza
Designed by: Holly Mckeon
Tel: 0117 342 3398
Email: by-band-sleeve@bristol.ac.uk

CTEU Bristol | University of BRISTOL | MRC Hubs for Trials Methodology Research ConDuCT-II Hub | Funded by NHS National Institute for Health Research

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