P384

Family perspectives on the feasibility of a corticosteroid induction regimen randomised controlled trial in juvenile idiopathic arthritis: results of a qualitative study

Frances Sherratt[1], Louise Roper[1], Eileen Baildam[2], Matthew Peak[2], Flora McErlane[3], Simon Stones[4], Bridget Young[1]
[1]University of Liverpool; [2]Alder Hey Children's NHS Foundation Trust; [3]Great North Children's Hospital, Newcastle Hospitals NHS Foundation Trust; [4]University of Leeds
Correspondence: Frances Sherratt
Trials 2017, **18(Suppl 1):**P384

Background
Corticosteroids (CS) are key to achieving rapid disease control in children and young people (CYP) presenting with new or flaring juvenile idiopathic arthritis (JIA). Efficacy, duration of action and side effect profiles vary with the route of administration. Current routes of CS administration are based on physician and patient preference, rather than scientific evidence. A randomised controlled trial is needed to ascertain the most effective routes and doses of CS. This paper will report on the feasibility of a potential CS induction regimen randomised controlled trial (RCT) in JIA from the perspective of CYP and their families.
Methods
Semi-structured in-depth interviews were conducted with a purposive sample of CYP with JIA and their families, recruited via rheumatology clinics across the UK. All CYP and their families had recent (<12 months) experience of CS treatment. The Framework Method was used to support thematic analysis of the data.
Results
Findings will be reported on CYP'S and parents' experiences of four different CS delivery routes, treatment preferences and willingness to participate in a CS induction regimen RCT, randomising patients between different steroid delivery routes and dose regimes. CYP's and parents' questions about the planned RCT and their recommendations regarding its design will also be reported.
Discussion
The findings from this qualitative study will inform judgements about the feasibility and design of a future RCT of CS induction regimens for JIA. Corticosteroids are a very effective treatment for flaring JIA but carry significant and challenging side-effects. The views and experiences of CYP with JIA are an important outcome of this study and are key to informing the feasibility and acceptability of a future RCT from the patient perspective. Methodological issues about the validity of pre-trial feasibility studies for informing decisions about potential future trials will also be considered.

P385

Overtreatment of DCIS – 4 years on from the marmot review - progress with the LORIS trial

Jennie Young[1], Adele Francis[2], Jeremy Thomas [3], Matthew Wallis[4], Andrew Hanby[5], Lesley Fallowfield[6], Valerie Jenkins[6], Lucy Matthews[6], Patricia Fairbrother[7], Maggie Wilcox[7], John Bartlett[8], Lucinda Billingham[9], Sarah Bowden[9], Claire Gaunt[9], Daniel Rea[9], Tracy Roberts[9], Sarah Pinder[10]
[1]University of Birmingham; [2]University Hospitals Birmingham; [3]Western General Hospital; [4]Addenbrooke's Hospital; [5]University of Leeds; [6]SHORE-C, Brighton and Sussex Medical School; [7]Independent Cancer Patients' Voice; [8]Ontario Institute for Cancer Research; [9]University of Birmingham, Cancer Research UK Clinical Trials Unit; [10]King's College London
Correspondence: Jennie Young
Trials 2017, **18(Suppl 1):**P385

The Marmot independent review of breast screening report published in 2012 concluded that the breast screening programme saves lives but significant overtreatment exists [1]. The review called for randomised clinical trials to address overtreatment of screen-detected DCIS.
More recently, Sagara et al. [2] conducted a retrospective longitudinal cohort study in the USA investigating the survival benefit of breast surgery for DCIS. They found no significant difference in breast cancer specific survival between patients who had surgery and those who did not in the low grade DCIS group.
LORIS is a multi-centre, randomised controlled phase III trial of surgery versus active monitoring in patients with low risk DCIS designed to address the problem of overtreatment.
An independent patient advocate group (Independent Cancer Patients' Voice) have been involved in the study since conception and provided a direct patient perspective throughout the LORIS Trial.
Key eligibility criteria are; women aged 46 years and over with screen-detected or incidental microcalcification with no previous invasive breast cancer, no comedo necrosis and low risk disease confirmed by Central Digital Histopathology Review. The primary outcome is ipsilateral invasive breast cancer free survival up to 5 years.
34 sites have opened to recruitment across the UK, with enthusiasm, commitment and support evident from the site research teams. Patients have responded favourably to the trial and the opportunity to contribute to ground breaking research. Patients found the Patient Information DVD informative and welcomed receiving information early on in the patient pathway.
Reasons patients gave for participating in the trial include "the trial offered the best treatment options" and that "others would benefit from the results of the trial". Patients have also commented that they welcome the opportunity for independent pathology review of their biopsies; a key quality assurance element of the trial. Feedback from sites highlights the difficulty in conveying to patients the rationale of replacing surgery with active monitoring, with 30% of patients stating a preference for surgery. To address this, regular communication workshops are offered, phone-in sessions allow sites to share best practice and frequent newsletters offer hints and tips to aid recruitment. Media channels are being explored to raise public awareness of the overtreatment of DCIS. Dissemination of this information will help to engage future LORIS patients.
Following on from the successful launch of LORIS in the UK, the trial is now leading the way internationally. LORIS is collaborating with COMET (USA) and LORD (Netherlands).
Collaborative efforts and feedback from site staff, patients and oversight committees during the LORIS feasibility phase has allowed us to establish LORIS as a world leading trial addressing the overtreatment of DCIS.
The LORIS Trial is funded by the National Institute for Health Research Health Technology Assessment programme.

References
[1] Marmot MG, Altman DG, Cameron DA, Dewar JA, Thompson SG, Wilcox M. The benefits and harms of breast cancer screening: an independent review. Br J Cancer. 2013;108(11):2205–40.
[2] Sagara Y, Mallory MA, Wong S, Aydogan F, desantis S, Barry WT, et al. Survival Benefit of Breast Surgery for Low-Grade Ductal Carcinoma In Situ: A Population-Based Cohort Study. JAMA surgery, 2015.

P386

Statistical analysis plans for internal pilots in randomised controlled trials

Cliona McDowell[1], Evie Gardner[2], David Harrison[3], James McNamee[4], Daniel F. McAuley[5]
[1]Northern Ireland Clinical Trials Unit; [2]Northern Ireland Clinical Trials Unit, Belfast; [3]Intensive Care National Audit & Research Centre, London; [4]Regional Intensive Care Unit, Royal Victoria Hospital, BHSCT and Wellcome-Wolfson Institute for Experimental Medicine, Belfast; [5]Northern Ireland Clinical Trials Unit, Regional Intensive Care Unit, Royal Victoria Hospital, BHSCT and Wellcome-Wolfson Institute for Experimental Medicine, Belfast
Correspondence: Cliona McDowell
Trials 2017, **18(Suppl 1):**P386

Background
It is common practice for clinical effectiveness trials to include an internal pilot but guidance on how they should be analysed is lacking. The REST study is a pragmatic randomised controlled trial to determine whether Veno-Venous Extracorporeal Carbon Dioxide Removal