


# Short or Long Antibiotic Regimes in Orthopaedics (SOLARIO): a Randomised Controlled Open-Label Non-Inferiority Trial of Duration of Systemic Antibiotics in Adults with Orthopaedic Infection Treated Operatively with Local Antibiotic Therapy

**CURRENT STATUS:** ACCEPTED

 Trials  BMC

Maria Dudareva  
Oxford University Hospitals NHS Foundation Trust

 [maria.dudareva@ouh.nhs.uk](mailto:maria.dudareva@ouh.nhs.uk) *Corresponding Author*  
ORCID: <https://orcid.org/0000-0002-3139-7237>

Michelle Kümin  
Nuffield Department of Medicine, University of Oxford

Werner Vach  
Department of Orthopaedics and Traumatology, Universitaetsspital Basel, Switzerland

Klaus Kaier  
Albert-Ludwigs-Universitat Freiburg

Jamie Ferguson  
Oxford University Hospitals NHS Foundation Trust Nuffield Orthopaedic Centre

Martin McNally  
Oxford University Hospitals NHS Foundation Trust Nuffield Orthopaedic Centre

Matthew Scarborough  
Oxford University Hospitals NHS Foundation Trust

## DOI:

10.21203/rs.2.13884/v1

## SUBJECT AREAS

*Orthopedics* *Translational Medicine*

## KEYWORDS

*Osteomyelitis, Prosthetic joint infection, Diabetic foot, Antibiotic, Duration, Carrier, Revision, Local antibiotic therapy*

## Abstract

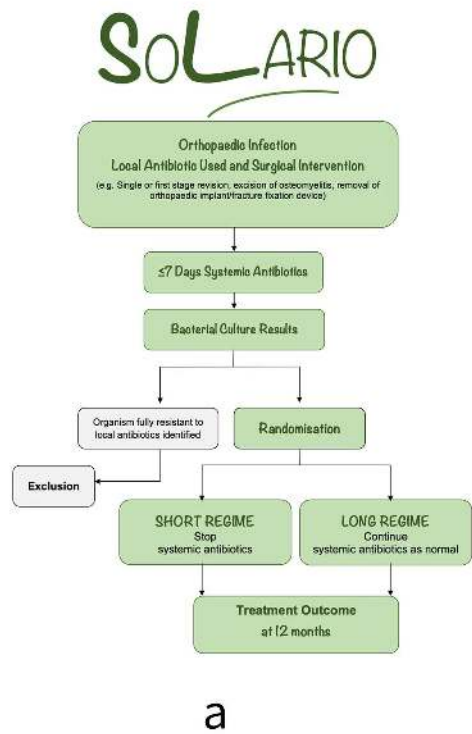
Background Orthopaedic infections such as osteomyelitis, diabetic foot infection and prosthetic joint infection, are most commonly treated by a combination of surgical debridement and a prolonged course of systemic antibiotics, usually for at least 4 -6 weeks. Use of local antibiotics, implanted directly into the site of infection at the time of surgery, may improve antibiotic delivery and allow us to shorten the duration of systemic antibiotic therapy, thereby limiting the frequency of side effects, cost and selection pressure for antimicrobial resistance. Methods SOLARIO is a multi-centre open label randomised controlled non-inferiority trial comparing short and long systemic antibiotic therapy alongside local antibiotic therapy. Adult patients with orthopaedic infection, who have given informed consent, will be eligible to participate in the study provided that no micro-organisms identified from deep tissue samples are resistant to locally-implanted antibiotics. Participants will be randomised in a 1:1 ratio to receive either a short course ( $\leq 7$  days) or currently recommended long course ( $\geq 4$  weeks) of systemic antibiotics. The primary outcome will be treatment failure by 12 months following surgery, as ascertained by an independent Endpoint Committee blinded to treatment allocation. An absolute non-inferiority margin of 10% will be used for both per-protocol and intention-to-treat populations. Secondary outcomes will include probable and definite treatment failure, serious adverse events, treatment side-effects, quality of life scores and cost analysis. Discussion This study aims to assess a treatment strategy that may enable the reduction of systemic antibiotic use for patients with orthopaedic infection. If effective, this will be to the advantage of patients and contribute to antimicrobial stewardship.

## Full-text

Due to technical limitations, full-text HTML conversion of this manuscript could not be completed.

However, the manuscript can be downloaded and accessed as a PDF.

## Figures



TIMEPOINT	STUDY PERIOD						
	Enrolment <i>Before and up to 7 days after surgery</i>	Allocation 0	0	+6 weeks	+3-6 months	+12 months	Close-out <i>+12 months from last enrolment</i>
<b>ENROLMENT:</b>							
Eligibility screen	X						
Informed consent	X						
Allocation		X					
<b>INTERVENTIONS:</b>							
Short Systemic Antibiotics			X				
Standard (Long) Systemic Antibiotics							
<b>ASSESSMENTS:</b>							
EQ-5D-5L Questionnaire	X						X
Baseline Health Questionnaire	X						
Symptoms associated with treatment			X	X	X		
Systemic antibiotic use			X	X	X	X	
Duration of hospital admission				X			
Potential Primary Endpoint				X	X	X	X

Figure 1

1a. Flow diagram of participant enrolment, randomisation, treatment and follow-up within the SOLARIO study. 1b. SPIRIT Schedule of enrolment, interventions, and assessments in the SOLARIO study.

## Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

SOLARIO\_PIS\_v1.2\_MK\_18.01.19\_clean.docx