Hand And Wrist: AntImicrobials and Infection – burieD vs. exposed K-wiRes In Fracture fixaTion

WHY THIS RESEARCH?

Broken bones in the hand and wrist are very common in the UK. They usually happen at work, following a fall or during sports. Sometimes, when these bones are broken, surgery will be needed to fix them. This is usually the case if the bones have broken and fallen out of place. Fixing broken bones in the hand and wrist is routinely performed in the National Health Service (NHS), accounting for about half of all surgeries for hand and wrist injuries.

During the surgery, the doctors will move the bones back into the right place and then use metal wires to hold them. These wires fix the bones in place while they heal. Once the bones have healed, the wires are then removed.

When the wires are put in, the ends of the wires can either stick out of the skin or be buried under the skin. There are no reliable studies that tell us if one option is better for patients.

Both options have advantages and disadvantages. Wires buried under the skin might lower the risk of the hand or wrist becoming infected. This option is more expensive for the NHS and requires another surgery to remove the wire. Wires sticking out of the skin make them easy to remove and are cheaper for the NHS, however, patients might have a higher chance of getting an infection. This is important, as infections after surgery can be very serious. Infections can mean people need to come back into hospital for antibiotics and possibly further surgeries. It can also mean that their hands and wrists will recover slower, affecting work and daily life.

WHAT SORT OF STUDY IS THIS?

This is a multi-centre prospective randomised superiority trial of buried vs exposed wires in hand and wrist fractures in adults aged 16 years and over with fractures of the hand or wrist who require fixation with K-wires.

STUDY DESIGN.

This is a study to compare the two options to work out which gives the best result. Participants with broken bones in the hand or wrist that need fixing with metal wires will be randomly chosen to have their wires buried or left sticking out. By choosing randomly, the two groups will be equal, except for whether the wire end is buried or left sticking out. The number of infections will be checked after 90 days and hand and wrist recovery will be checked at 6 months.

The study will recruit 470 participants (235 in each of the two groups) with fractures of the hand or wrist from a minimum of 22 research sites in the UK.

SYNOPSIS

Study Title	Hand And Wrist: Antimicrobials and Infection – burieD vs. exposed K-wiRes In Fracture fixaTion
Chief Investigator	Mr Justin Wormald
Co-Chief Investigator	Mr Matthew Gardiner
Acronym	HAWAII-DRIFT
Funder	National Institute for Health and Care Research (NIHR) RfPB NIHR207194
IRAS	342133
CPMS	61682
Study Design	Multi-centre, two arm, parallel design, superiority, randomised controlled clinical study.
Study Participants	Adults aged 16 years and over with fractures of the hand or wrist who require fixation with K-wires INCLUSION • Age 16 years and above • Open or closed hand/wrist fracture(s) which, in the opinion of the treating clinician, requires manipulation under anaesthetic and fixation with K-wires EXCLUSION • Insufficient soft tissue cover to bury the wire • Presence of overlying or adjacent skin infection/disorder • Injury is more than 2 weeks old • Inability of participants to adhere to the trial procedures and/or follow-up procedures
Sample Size	470 participants
Recruitment Duration	15 months
Intervention	Buried K-Wires
Comparator	Exposed K-Wires
Duration of intervention	K-wires will usually remain in place for 3 to 6 weeks
Primary Objective	To compare the risk of SSI by 90 days post-randomisation between buried and exposed K-wires in patients treated for hand and wrist fractures
Secondary Objectives	To compare: a) Upper extremity function and pain between treatment groups b) Health-Related Quality of Life between treatment groups c) Risk of complications between groups *d)* Assess costs and comparative cost-effectiveness between treatment groups