



## **Synopsis**

## Microfracture with or without collagen scaffold insertion for adults with chondral or osteochondral defects of the knee: the SISMIC RCT and its challenges during and after the COVID-19 pandemic

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## Plain language summary

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## Plain language summary

Knee injuries are common and can lead to pain and disability. The end of the bone in the knee joint is lined with a material called cartilage. Damaged cartilage rarely heals naturally. Around 10,000 people a year in the United Kingdom need surgery to fix the injury. One way to do this is with an operation called 'microfracture'. The surgeon makes small holes in the bone which allows blood and bone marrow to seep out, to help the area heal and encourage cartilage growth. A piece of material called a 'scaffold' can also be attached. Like cartilage, scaffolds are made of collagen. Scaffolds cost approximately £900 each, so it is important to establish if they help the knee heal and result in better outcomes for patients and are cost-effective for the National Health Service.

The SISMIC study planned to recruit 176 people. Half would have had the scaffold and the other half would not. We planned to keep in contact with participants for 2 years and collect information about quality of life, symptoms and pain, complications, need for further surgery and costs.

Unfortunately, the COVID-19 pandemic meant that less people had knee surgery, and this continued after the peak of the pandemic. The funder, as part of a national process to help clinical research recover, decided to stop funding this study at the end of 2022. When the study closed, 10 people had been recruited, but none had been followed up for 2 years. This means that we cannot decide if scaffold should be used. Another study to answer this question could be feasible when the number of operations returns to pre-pandemic levels, as we found that SISMIC was acceptable to patients and surgeons. Everyone invited to take part agreed to do so, and they all received the treatment they were supposed to.