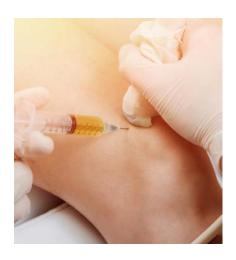


SCUIpTOR study Stem cell injections for knee osteoarthritis



What is this study about?

The SCUIpTOR trial is a research study aiming to see if stem cells injected into the knees of people with knee osteoarthritis (OA) can improve their symptoms compared with placebo. The medical opinion about stem cell therapy for treating osteoarthritis is mixed due to limited research evidence and considerable costs. So our aim is to find out whether or not stem cell injections into the knee improve symptoms and slow disease progression in people with mild to moderate knee OA. The stem cells we use originally came from a healthy donor/master cell bank and are made following standard manufacturing process to make sure they are safe and standardised.

If the study is suitable for you, you will have a 50% chance of being allocated to either group and receive:

Active group: three knee intra-articular injections of allogeneic MSCs (stem cells) performed at baseline, week 3 and 52.

Placebo group: three knee intra-articular injections of saline performed at baseline, week 3 and 52.

As a participant, you will be asked to attend seven study visits and complete online surveys regularly over 24 months.



The study is suitable for people who:

- Are aged 40 years or older and living in Australia (and have a Medicare number)
- Have knee OA and moderate pain assessed by the visual analogue pain intensity scale from 0 (no pain) to 100 (worst pain possible)
- Have internet access and an active email account
- Are willing to stop or maintain knee OA treatments (e.g. supplements, physiotherapy) for the duration of the study
- Are willing to stop or minimise the use of anti-inflammatory drugs (e.g. Aspirin, Nurofen, Ibuprofen, Mobic, Voltaren, etc.) and other analgesics (e.g. opioids), except for paracetamol (only for rescue pain relief) for the duration of the study. This includes stopping all pain medications for one week before each study assessment.
- Able to speak and read English sufficiently to understand study procedures, complete questionnaires and provide informed consent.
- Are willing and able to travel for the study required physical visits.

Study Safety

This study has been approved by the University of Sydney (2020/119) and the University of Tasmania's (21868) Human Research Ethics Committee (HREC).

Am I eligible?

If you have knee pain due to osteoarthritis and live in Sydney or Hobart, please complete the online screening survey available at www.tinyurl.com/sculptor-trial to assess your eligibility.