

ZOLEDRONIC ACID FOR KNEE OSTEOARTHRITIS CONSENT

A randomised trial of zoledronic acid for osteoarthritis of the knee

1. I acknowledge that the nature, purpose and contemplated effects of the project so far as it affects me, have been fully explained to my satisfaction by the research worker and my consent is given voluntarily.
2. The details of the procedure proposed have also been explained to me, including the anticipated length of time it will take, the frequency with which the procedure will be performed, and an indication of any discomfort, which may be expected. I understand that my involvement includes the following components:
 - a. MRI scan at a screening appointment, 6 and 24 months.
 - b. X-ray at a screening appointment.
 - c. An infusion (needle) of zoledronic acid (with or without prednisolone) or placebo at month 0 and 12.
 - d. Collection of a small amount of blood (approximately 9 ml) and urine at screening and 6 months, to be taken by a qualified venepuncturist. This is to assess electrolytes, renal function, calcium, vitamin D and cartilage markers.
 - e. Storage of blood and urine samples.
 - f. Questionnaires about knee pain, knee function, pain at other sites, joint replacement surgery, and medications at months 0, 3, 6, 12, 18, and 24 months.
 - g. Questionnaires about quality of life and measurement of height, weight and leg strength at months 0, 6, and 24.
 - h. Prescription of vitamin D supplements if my serum vitamin D levels are <50 nmol/L as this is required for zoledronic acid treatment
3. I understand that there are the following risks or possible discomfort:
 - a. I understand that a small amount of radiation exposure is associated with a knee x-ray; and that this amount of radiation is unlikely to be associated with increased risk of disease and is much less than the current National Health and Medical Research Council guidelines;
 - b. Having blood taken causes minimal risk, but there may be a chance of discomfort and bruising.
 - c. I understand that zoledronic acid treatment has side effects; and that serious side effects are rare.

- d. I understand that MRI scans may be claustrophobic, but are otherwise considered safe.
4. I have been informed that if my MRI scan shows a bone marrow abnormality I will be asked to continue in the study. If my MRI scan is normal I will not be asked to continue with the study.
5. I give consent for my medical records to be made available from the National Joint Registry for the purpose of checking on any knee joint replacement surgery following study completion.
6. Although I understand that the purpose of this research project is to improve the quality of medical care, it has also been explained that my involvement may not be of any benefit to me.
7. I understand that the research gathered in this study may be published. I am informed that no information regarding any medical history will be divulged and the results of any tests involving me will not be published so as to reveal my identity.
8. I understand that my involvement in the project will not affect my relationship with my medical advisers in their management of my health. I also understand that I am free to withdraw from the project at any stage and any of my data/specimens that have been collected. My withdrawal will not affect my legal rights, my medical care or my relationship with the hospital or my doctors.
9. I understand that I will be given a signed copy of this patient information sheet and consent form. I am not giving up my legal rights by signing this consent form.
10. I understand that the trial will be conducted in accordance with the latest versions of the *National Statement on Ethical Conduct in Human Research 2007* and applicable privacy laws.

CONSENT

Name of patient _____

Signature of patient _____ Date _____

I have explained this project and the implications of participation in it to this patient and I believe that the consent is informed and that he/she understands the implications of participation.

Name of investigator _____

Signature of investigator _____ Date _____